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Evaluation of physiotherapy intervention for non-specific sub-acute and chronic low back pain

By

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A thesis submitted in partial fulfilment of the
requirements for the degree of Doctor of Philosophy in
Medicine

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ABSTRACT

This thesis investigates routine physiotherapy management of patients with sub-acute and chronic non specific low back pain.

In a pragmatic multi-centre trial patients were randomised to receive a course of physiotherapy treatment or advice following a bio-psychosocial model. Disease specific, patient specific and generic measures were used to assess outcome.

The 286 patients recruited in the trial had, on average, minimal to moderate low back pain disability. Patients reported enhanced perceptions of benefit in the physiotherapy group but there was no evidence of a long term effect in any other outcomes. There were no differences between the groups in NHS costs although patients in the physiotherapy group incurred significantly higher out of pocket expenses. Further analysis of the outcome data confirmed that the primary outcome measure (Oswestry Disability Index) was the most responsive instrument because it was able to detect deterioration as well as improvement.

As the trial demonstrated no additional benefit of physiotherapy over brief advice, it was important to investigate the effectiveness of the latter. A systematic review found limited evidence that brief bio-psychosocial advice was more effective in reducing fear avoidance and improving back beliefs in patients with acute and sub-acute low back pain compared with traditional medical advice. There was no direct evidence to support the use of brief bio-psychosocial advice (2 sessions or less) for reducing pain or disability.

This thesis describes research that has contributed to European guidelines for the management of chronic low back pain and reviews extensively the literature that seeks to evaluate physiotherapy practice. The clinical implication of this research is that for patients with non specific low back pain of mild severity, brief advice is likely to be as effective as prolonged physiotherapy intervention. The extent to which a single session of advice is more effective than no intervention needs further assessment.

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LIST OF ABBREVIATIONS AND GLOSSARY OF TERMS

LBP = Non-specific low back pain

RCT= Randomised controlled trial

ODI= Oswestry Disability Index

RMDQ = Roland and Morris Disability Questionnaire

PSAQ= Patient Specific Activity Questionnaire

CONSORT (Consolidating Standards of Reporting Trials) = The CONSORT statement was developed with the aim of improving the reporting of randomised controlled trials. It includes a quality criteria check list and flow diagram and was intended for use in writing, reviewing or evaluation of randomised controlled trials.

QUORUM (Quality of reporting of meta-analysis) = The QUORUM statement was developed with an aim to improve the reporting of systematic reviews. It encourages authors to provide adequate information regarding searches, selection, validity assessment, data abstraction, study characteristics, quantitative data synthesis and trial flow.

Bio-psychosocial The word bio-psychosocial refers to a model that takes into account the person, his or her health condition and the interaction of physical, psychological and social factors in back pain disability.

Fear avoidance This refers to fear of pain that results in avoidance of movement that perpetuates pain behaviours (over exaggerated expression of pain through movement or gestures) and experiences even in the absence of demonstrable pathology.

Type 1 error A term that means a statistically significant result is found, and a null hypothesis is rejected, when the null hypothesis is true (a false positive result) A type 1 error is also referred to as α .

Type 2 error A term that means a statistically significant result is not found, and a null hypothesis is accepted when the null hypothesis is false (a false negative result). A type 2 error is also referred to as β .

Sensitivity to change. A term used in the context of this thesis to describe responsiveness of outcome measures. Sensitivity to change refers to an outcome's ability to correctly classify improved patients according to an external marker of change.

Specificity to change. A term used in the context of this thesis to describe responsiveness of outcome measures. Specificity to change refers to an outcome's ability to correctly classify non-improved patients according to an external marker of change.

PUBLICATIONS

The work presented in this thesis has been published in the following journals;

1. **Frost H, Lamb SE, Doll H, Taffe Carver P, Stewart-Brown S.** Randomised controlled trial of physiotherapy compared with advice for low back pain. *BMJ* 2004; 329:708-711.
2. **Frost H Lamb SE.** A critical appraisal and defence of the Oxfordshire low back pain trial. *Physiotherapy* 2005; 91 1-5, 1-3.
3. **Rivero-Arias O, Gray A, Frost H, Lamb SE, Stewart-Brown S.** Cost-Utility analysis of physiotherapy treatment compared with advice in low back pain. *Spine* 2006;31,12.1381-8
4. **H Frost, S Lamb, S Stewart Brown,** Responsiveness of a patient specific outcome measures compared with the Oswestry Disability Index and the Roland and Morris Disability Questionnaire for patients with sub-acute and chronic low back pain. *Spine* 2008;33(22):2450-7.

STATEMENT OF CONTRIBUTION

Helen Frost was the chief investigator on the two project grants (total cost £86 454) from the Arthritis Research Campaign which supported the randomised controlled trial described in this thesis.

Sarah Stewart Brown was a co-applicant on both grants and was involved in the trial design and implementation from the outset.

Sallie Lamb was co-applicant on the 2nd extension grant and was involved in managing the trial at that stage. All grant holders contributed to the interpretation and publication of the results of the trial.

Helen Frost: -

- Led the design and operational management of the trial.
- Recruited physiotherapy departments to the study.
- Completed the request for ethical approval from the Oxfordshire Nursing and Allied Professions Research Ethics Committee and the West Berkshire Local Ethics Committee.
- Organised collaborators meetings, liaised with physiotherapy managers, general practitioners and consultants involved in the trial, wrote agendas and chaired the collaborators meetings.
- Managed the trial throughout the study duration with the support of a part-time trial administrator (Jane Hainsworth for the first eight months and subsequently Tricia Taffe Carver) and part-time trial research therapists

(Farida Barma, Kirstie Haywood, David Beard, Mary Pinkney, Liz Walker, Helen Dawes, Val McKee and Helen Tyra) all of whom she recruited.

- Wrote letters and information leaflets for patients and their general practitioners.
- Wrote the training documents for the trial research therapists and clinicians.
- Trained the part time trial research therapists to identify patients from the waiting lists.
- Selected all the outcome measures, and produced the assessment questionnaires used in the trial.
- Created the data file into which the trial administrator entered the results of the baseline and follow up questionnaires.
- Cleaned and checked the data for outliers and missing values.
- Explored each variable using SPSS version 12.
- Developed and designed the outcome study in chapter 8 and carried out all the analysis using SPSS. (Including ANOVA and ROC analysis).
- Carried out all the work for the systematic review in chapter 9 including the design of the protocol, search for papers, analysis and interpretation.
(Hamish Simpson was the second assessor who scored the papers including in the systematic review).

Other collaborators who contributed to the multi-centre randomised controlled trial included:-

- Professor Alastair Gray (Health Economist, Health Economics Research Centre, Department of Public Health, University of Oxford) who advised on the collection of the cost data.
- Oliver Rivero Arias (Health Economics Research Centre, Department of Public Health, University of Oxford) who produced the table of costs but had no involvement in the development of the research protocol or questionnaires.
- Helen Doll (Statistician, Department of Public Health, University of Oxford) gave statistical advice and carried out the ANCOVA analysis for the trial in consultation with the chief investigator.

Introduction

Physiotherapy is the largest paramedical profession responsible for the management of back pain and direct costs of intervention within the NHS are high.¹ This thesis investigates the effectiveness of NHS physiotherapy interventions for patients with non specific low back pain.

The first chapter reviews the literature and justifies the need to evaluate routine NHS physiotherapy intervention. The second and third chapters describe physiotherapy interventions that are routinely used in the NHS and the evidence for their effectiveness prior to implementation of this research.

The following four chapters describe the rationale, design and results of a multi-centre randomised controlled trial that recruited patients between October 1997 and January 2001. No differences were found in disease specific or general health outcomes, at the twelve month follow up, between those who were randomised to a session of advice and those who had additional routine NHS physiotherapy intervention.

There were no differences found between the groups in NHS costs but patients in the physiotherapy group incurred significantly higher out of pocket expenses.

Discordance between the primary outcomes and patient perceived benefits of treatment led me to investigate the responsiveness of the main trial outcomes with an aim of verifying that they were valid measures of estimated change in the trial population. Chapter eight demonstrates that the primary trial outcome, the Oswestry Disability Index (ODI), was a responsive instrument for this population of patients

because it was able to detect deterioration as well as improvement and was specific to change.

Advice is an integral part of physiotherapy practice and the brief bio-psychosocial advice that was compared with routine physiotherapy in the trial is recommended in international back pain guidelines. However, advice is usually given in addition to other interventions and the trial results raised the question of how effective the brief advice was if given alone. I therefore searched the literature following the Cochrane guidelines to look for other trials that assessed brief bio-psychosocial education for patients with acute, sub-acute and/or chronic low back pain. Chapter nine reports the results of the systematic review that identified 21 publications reporting 19 trials in total. Two trials, with a total of 476 patients, met the inclusion criteria for the review. Limited evidence was found that brief bio-psychosocial education, delivered in one or two sessions, is more effective in reducing fear avoidance and improving back beliefs in patients with acute and sub-acute low back pain compared with traditional medical education. No strong evidence was found to support the use of brief intervention alone for reducing pain disability, work loss and recovery time or improving general health.

In chapter ten the thesis draws together and discusses the results of the randomised controlled trial, the responsiveness of the outcome measures and the systematic review in context with other research and back pain guidelines.

Chapter 1

Classification, epidemiology and cost of back pain

SYNOPSIS

This chapter describes the causes of low back pain and the most widely accepted methods of classification. It defines the aspects of low back pain of relevance to this thesis and reviews studies of the epidemiology and costs of this common disabling condition. It concludes that low back is the most common cause of physical disability in the working age population and the cost of physiotherapy intervention within the NHS is high.

DEFINITION AND CLASSIFICATION OF LOW BACK PAIN

Low back pain has been a problem to mankind for centuries with the first case reported around 2780 BC by an Egyptian physician.² Today the term is used to describe a range of signs and symptoms and in most patients a specific lesion cannot be found.³ It has been defined as pain, muscle tension or stiffness localised between the areas covered by the 12th rib and the gluteal folds, with or without leg pain.⁴ Doctors, physiotherapists, osteopaths, chiropractors and complementary therapists all use different methods of classification.^{5 6} A simple method, described by Waddell (1987) has gained international acceptance, divides back pain into three categories;

- Specific spinal pathology (e.g. tumours, infection cauda equina syndrome and inflammatory disorders such as ankylosing spondylitis)
- Nerve root pain or radicular pain

- Non-specific low back pain with or without referred leg pain.⁷

Specific pathology

A small percentage of patients with low back pain are found to have specific spinal pathology but serious pathological causes are rare. Survey data suggests that 4% of people seen with low back pain in primary care have compression fractures.⁸ A systematic review of cohort studies investigating the accuracy of clinical features and tests used to screen for malignancy in patients with low back pain identified six studies carried out in different settings. The prevalence of malignancy ranged from 0.1% (one patient out of 1030 from general practice referrals for lumbar spine x-rays), 0.7% (13 out of 1975 patients with low back pain from self referral public hospital), 1.5% (seven patients out of 282 attending accident and emergency departments) to 3.5% (18 out of 518 patients referred to orthopaedic surgeons).⁹ Specific causes of low back pain are shown in Table 1.

Cause of low back pain	Example
Infection	Epidural abscess, osteomyelitis
Tumours	Myeloma, secondary metastases
Inflammatory disease	Ankylosing spondylitis, Reiter's syndrome
Bone disease	Paget's disease or osteoporosis
Referred back pain	Abdominal disease, pelvic inflammatory disease, endometriosis, aortic aneurism
Cauda equina syndrome	
Disc herniation and vertebral fracture	

Table 1. Specific causes of low back pain

Nerve root pain

Nerve root pain can be caused by serious underlying spinal disease or a prolapsed intervertebral disc. Compression of the nerve root is usually localised to the dermatomal distribution (e.g. L5/S1 level causes pain and sensory disturbance in the foot or toes). However, 70% of patients with back pain have some referred pain to their legs that is not caused by nerve root irritation.

Non specific low back pain

In the majority of cases (85%) pain is not attributable to specific pathology or nerve root compression¹⁰ and is defined as non-specific. In some cases patients with non specific pain may have radiological signs of spondylolysis and spondylolisthesis (forward slipping of the lumbar vertebrae) but a considerable proportion of diagnosed patients are asymptomatic and therefore the radiological signs cannot always be directly related to the pathology.¹¹

Patients with non-specific low back pain may also present with referred pain (pain that radiates into the hips and legs) in addition to back pain. Referred pain can originate from a number of different tissues in the back including fascia, muscles, ligaments, periosteum, facet joints, intervertebral disc or epidural structures. It can be difficult to localise the exact source of referred pain affecting the hip, groin and thighs. This type of pain does not usually radiate beyond the knee.¹²

This thesis addresses physiotherapy intervention for non-specific low back pain with or without referred leg pain.

Classification of non-specific low back pain

The link between symptoms and pathology in non specific low back pain is not clear cut and a number of different approaches to classification have been proposed (e.g. fissures in the intervertebral disc, facet joint degeneration).^{6 13} While there is no consensus regarding the signs and symptoms that characterize non-specific low back pain,¹⁴ the most widely accepted criteria by health professionals is: Acute (<6 weeks duration; Sub acute (6 weeks to 3 months); Chronic (>3months).¹⁵

The six week threshold for acute low back pain is based on epidemiological data that suggests that 90% of patients with an acute attack are fully recovered within six weeks.¹²

This simple method of classification takes no account of severity, the dynamic and fluctuating nature of back pain or psychological and social factors.³ Croft et al. (1996) stress the limitations of this classification system and suggest that the most important concept is the pattern of back pain over long periods of the individual's life.¹⁶ Croft et al (1996) found that 90% of patients stopped consulting and returned to work after 6 weeks but 60% or more still had symptoms a year later.¹⁷ Back pain often manifests as 'a chronic problem with an untidy pattern of grumbling symptoms and periods of relative freedom from pain and disability interspersed with acute episodes, exacerbations and recurrences' that can be very difficult to manage.¹⁷

EPIDEMIOLOGY OF LOW BACK PAIN

The literature describing the epidemiology of back pain has three main components:

1. Studies describing and measuring the distribution of back pain.

2. Studies describing what might cause or influence different patterns of occurrence.
3. Studies evaluating the outcome of intervention designed to reduce its impact.¹⁶

This chapter reports on the first and second components. Evaluation of the outcome of intervention will be discussed in chapters three and ten.

Prevalence of low back pain

Epidemiological studies use the term prevalence to describe and measure the distribution of back pain and this is defined further as follows:

- Prevalence is the percentage of people in a known population who have back pain during a particular period of time.
- Point prevalence is the percentage who have back pain at a particular instance in time (e.g. on the day of interview).
- One year prevalence is the percentage of people who have back pain at some time during the study year.
- Lifetime prevalence is the percentage who report pain at some time in their life.
- Incidence is the percentage of a known population who develop back pain within a given time.¹²

Assessment of prevalence in a population is hampered by the lack of a clear definition. Prevalence estimates are all based on self-reported pain, a symptom rather than an objective sign that can be validated against some external criterion.¹⁶

Reviews of the epidemiology of back pain

The European back pain guidelines identified six reviews describing the epidemiology of low back pain.¹⁸ The high number of patients with recurrent low back pain made the estimation of the prevalence uncertain. Two surveys investigated chronic low back pain in Canada and Sweden.^{19 20} The Canadian survey included 2184 adults and reported that 50% of respondents had experienced low intensity back pain within the previous six months.²⁰ The prevalence of chronic low back pain (pain lasting for 3 months or more) in the Swedish study was 23%. A summary of the prevalence rates from various reviews are shown in Table 2.²¹

Estimated prevalence	Range
Point	12-33%
1 year	22-65%
Lifetime	11-84%

Table 2. Summary of estimated prevalence rates for back pain in the general population of Europe and the USA.

At any time point one in five people are reported to have back pain within the last month and one third of people with an acute episode of low back pain are reported to experience symptoms for more than four weeks.^{22 23} After an initial episode of low back pain 44-78% of people report relapses of pain and 11-12% became disabled. Eighty to ninety percent of patients recovered spontaneously from a new episode of back pain within six weeks without any medical intervention.^{10 12}

UK Surveys

In a well conducted, large UK study patterns and predictors of back pain and health care use were investigated in 7699 adults aged 18-75 years.²⁴⁻²⁶ The main findings were;

- 60-80% of people get back pain at some time in their lives.
- Most clinical attacks settle rapidly but residual symptoms and recurrences are common.
- 35-40% of people report low back pain lasting 24 hours or more each month.
- 15-30% of people have some low back pain symptoms each day.
- One month prevalence was reported to be 39%.
- The strongest predictor of a further episode of low back pain was a history of previous episodes.

In another large population survey of householders in four southern English counties (n=13042) back pain was reported as the most common cause of physical disability in the working age population and one of the most debilitating in terms of population impact on reduction in health related quality of life in the UK.²⁷

DISABILITY CAUSED BY LOW BACK PAIN

The most important consequence of low back pain is its impact on peoples' lives.

Low back pain has always been a common symptom but it is the disability associated with it that constitutes a major public health problem in western societies.

The disability, rather than the incidence of low back pain, escalated dramatically during the 1980's with statistics indicating approximately 3.6 million people suffering with chronic low back pain in the United Kingdom.^{12 28} In the 1980's time

off work due to low back pain increased by 40%, while time off work for all other complaints only increased by 5.6% (DHSS, 1989).¹² The DHSS statistics for 1991-1992 showed 81 million days sickness and invalidity benefit paid for back incapacities. In 1994-5, 194000 new awards of social security benefits were made for back related incapacity accounting for more than one in seven such awards. However, there was no evidence to suggest that the prevalence of non-specific low back pain was increasing at that time. The increase in claims for low back pain disability were thought to be a product of modern patterns of work and compensation.^{7 29} Recent evidence suggests that the number of people claiming back pain related disability benefits have dropped since the 1990's by as much as 42%. This is more likely to be due to change in incapacity benefit and the rules regarding eligibility than to change in the incidence of back pain per se.¹²

COST OF LOW BACK PAIN

Three large UK surveys have estimated the cost of low back pain to the NHS and society.¹ Their estimates vary depending on the methods used. The Clinical Standards Advisory Group on Back Pain (CSAG) based estimates on limited epidemiological evidence.³⁰ Total costs of back pain within the NHS were estimated to be £480 million (95% confidence interval £356 to £649 million) in 1993. In another survey carried out at a similar time, the York Centre for Health Economics estimated total costs of back pain within the NHS in the period 1992/1993 to be £324 million (£265 to £382 million) with physiotherapy costs at £24 to £36 million.³¹

The direct health care costs of low back pain in 1998 were estimated by Maniadakis and Gray (2000)¹ using data from a survey of a randomly selected sample of 6000 adults in Great Britain.³² The use of a range of health services attributable to the disease were estimated and valued. These included costs of general practitioners, private consultants, physiotherapy (private and NHS), osteopathy, chiropractic treatment, other specialists, hospital out-patient visits, cost of accident and emergency attendances, over the counter and prescribed medication, cost of in-patient days and day cases, radiology and imaging, community health and social services and employment and informal care costs. The direct health care costs were estimated to be £1632 million, with physiotherapy accounting for £251 million (£150.7 million NHS costs and £100.5 million private costs). These costs were considerably higher than previously reported because the analysis was based on more precise data. The physiotherapy costs were derived from data reporting that 9% of those suffering from back pain visit a physiotherapist either privately or via the NHS.³² This implies that 1.6 million adults received physiotherapy for low back pain per annum at that time. There is no evidence to confirm that these figures have changed in the last decade.

SUMMARY

- Back pain is the most common cause of physical disability in the working age population and non-specific low back pain is the most common type of back pain.
- Estimates of the prevalence of non specific back pain vary due to differences in definition and methods of classification but affects in the order of 60-80% of patients at some time in their lives.
- There is no evidence to suggest that the prevalence of non-specific back pain is increasing but the disability associated with this condition rose dramatically in the 1980's.
- The costs of NHS and private physiotherapy treatment for back pain are high.

Chapter 2

Physiotherapy management of low back pain

SYNOPSIS

This chapter describes the range of different approaches to physiotherapy assessment and intervention in broad terms. It covers interventions commonly used by physiotherapists working in the NHS and provides a definition of terms like ‘exercise’ and ‘manipulation’ which are used loosely in the literature. The aim of the chapter is to describe the interventions referred to throughout this thesis that are commonly used in the UK NHS.

BACK PAIN ASSESSMENT

Physiotherapy treatment is based on the findings of patient assessment and this includes a full history and physical examination of joints, soft tissue and muscle function. Methods of assessment vary depending on the training the physiotherapist has received,⁶ but all assessments should include diagnostic triage¹² which aims to place patients in one of the three categories of the Waddell classification: non specific low back pain, radicular syndrome or specific pathological change. This is essential to identify symptoms of serious pathology (commonly known as red flags) such as cauda equina syndrome, infection and tumours which need referral to specialists for immediate treatment (Table 3).¹² The straight leg raise test is recommended for assessing neurological risk factors (radicular syndrome).

PSYCHOLOGICAL RISK FACTORS

Psychological factors are important in back pain management because they increase the risk of developing pain and influence how people react to their back pain symptoms.³³⁻³⁵

There is evidence to support the inclusion of psychological factors in the assessment of back pain. Pincus et al. (2002) carried out a systematic review of prospective cohort studies in low back pain with the aim of evaluating the evidence for psychological factors in the development of chronic pain. Six out of 25 papers met the quality criteria for inclusion in the review. Psychological factors, such as distress and depressive mood, were implicated in the transition to chronic low back pain.³⁶

In a large well conducted study Linton et al.(2005)³⁷ carried out a comprehensive evaluation of background, individual and workplace psychological risk factors to investigate their relationship with spinal pain. Participants were randomly selected workers from the general population of Sweden, where 372 had not experienced pain during the past year, and 209 had experienced considerable pain. A cross-sectional comparison of these groups indicated that the most potent risk factor was psychological distress.³⁸

Psychological factors can make a person more aware of back pain or more likely to seek help.¹² Additionally they may aggravate and perpetuate the pain. Most physiotherapists aim to identify any potential psychological risk factors (termed yellow flags³⁹) when assessing for the development of chronic disability. Common psychological risk factors are presented in Table 3.

Red flag indicators of serious spinal pathology	Yellow flag indicators for psychological factors
Cauda equina syndrome Presentation under age 20 or onset over 55 Non-mechanical pain Thoracic pain Past history of carcinoma, steroids, HIV Unwell, weight loss Widespread neurological symptoms Structural deformity Indications for radicular pain Unilateral leg pain>low back pain Radiation to foot or toes Numbness and paraesthesia in same distribution Straight leg raise test induces more leg pain Localised neurology (limited to one nerve root)	A belief that low back is harmful or potentially severely disabling Fear avoidance behaviour and reduced activity levels Tendency of low mood and withdrawal from social interaction Expectation of passive treatment rather than a belief that active participation will help

Table 3.Summary of assessment for diagnosis of back pain

PHYSIOTHERAPY INTERVENTIONS

A number of different interventions have evolved over the years to treat low back pain. These may be active, passive or a combination of the two. Passive approaches

involve a range of different techniques carried out on the patient by the therapist.

Active approaches require active involvement by the patient in some form, either by exercising or changing behaviour.

Physiotherapists use the terms physical activity, exercise and physical fitness to describe active interventions, but they are often used loosely and interchangeably. In the context of this thesis they will be defined as follows.

Physical activity is bodily movement produced by contraction of skeletal muscle that substantially increases endurance expenditure.⁴⁰

Exercise, a type of physical activity, is defined as planned structured and repetitive bodily movement done to improve or maintain one of more components of physical fitness.⁴⁰ Exercise programmes are usually prescribed for patients individually and may be carried out at home or in a clinic. The term 'exercise' is used to include a range of methods from isometric stabilising exercise through to intensive aerobic fitness programmes. Exercise programmes aim to strengthen specific muscles, stretch soft tissue, gain general mobility and improve co-ordination of muscles.

Physical fitness is a multidimensional concept that has been defined as a set of attributes that people possess or achieve that relates to the ability to perform physical activity, and is comprised of skill-related, health related and physiological components.⁴⁰ Physical fitness programmes vary in intensity, design and delivery and are generally supervised in a group but can be offered to patients on an individual basis. They usually include aerobic exercises with an aim to improve overall cardiovascular fitness as well as specific exercises.

ACTIVE INTERVENTIONS

Backschools

Backschools originally developed in Sweden in the early 1980's.⁴¹ This intervention is defined as an education and skills programme, sometimes including exercise, in which all lessons are given in groups and supervised by a paramedical therapist or medical specialist.⁴² There are common themes in the educational component of back schools that include; the anatomy of the spine, theories of the aetiology of low back pain, role of posture, ergonomics, exercise, the effect of back pain on social functioning and work, and changing unhelpful beliefs about back pain. The type of back pain advice is thought to be important and more emphasis has recently been placed on positive reinforcement of activity rather than negative advice about activities that should be avoided.⁴³

Brief educational intervention

Brief educational intervention (as distinct from backschools) includes interventions that involve contact with a healthcare professional (1 or 2 sessions). Education has always been an integral part of physiotherapy management and the aim is to help patients cope with their back pain and deal with further episodes. There are numerous types of information available for patients in the form of booklets, videos, internet sites and leaflets many of which are contradictory.⁴⁴ Prior to 1980 educational material for back pain was based on medical and mechanical information that suggested restriction of activity and focused on relief of pain. In the 1980-90's research suggested that this method of delivering education advice

had little long term effect.^{43 45 46} An alternative bio-psychosocial model has developed that focuses on the disability caused by back pain and emphasizes the importance of changing beliefs and behaviour.⁴⁷ This model is described and discussed in more detail in chapters nine and ten of this thesis.

McKenzie approach

The McKenzie system is a method of evaluating and treating spinal disorders developed by New Zealand Physiotherapist Robin McKenzie. It is practiced extensively throughout the world on five continents and in 22 countries. Using this system, clinicians perform a thorough history and evaluation, observing the patient's response to repeated, end-range spinal motions. The Mckenzie method categorises patients into three broad syndromes following observation of active movement and posture;

- Postural (resulting from poor posture).
- Dysfunction (excessive stretching of inelastic tissues).
- Derangement (believed to be caused by displacement of nucleus material of the disc).⁴⁸

Patients are then treated with a combination of postural advice, specific exercises (predominately passive extension and flexion) stretching exercises and in some cases, where exercise alone is not considered effective, spinal mobilisation or manipulation (a passive intervention described below).

The most common diagnosis is the derangement syndrome. This is thought to result from an alteration in the structure and mechanics of the intervertebral disc. In the derangement syndrome, positions and exercises that "centralise" the pain (move it

away from the lower limbs) are emphasized. Movements and positions that cause referred pain into the buttocks or lower limbs are avoided. Patients are encouraged to take responsibility for their own improvement and postural advice is central to the treatment. Patient advice booklets which describe stretching exercises are usually offered to patients with the aim of preventing recurrence and encouraging self management.

Spinal stabilisation exercises (core strengthening exercises)

The terminology used to describe spinal stabilisation exercises varies in the literature. Terms include; lumbar stabilisation, dynamic stabilisation, motor control (neuromuscular) training, neural spine control, muscular fusion and trunk stabilisation.⁴⁹ The approach is based on knowledge of the way in which different muscles provide stability for the spine in normal situations and research that has demonstrated localised dysfunction in the deep muscles of patients with low back pain.⁵⁰⁻⁵² The exercises focus on retraining and strengthening a precise co-contraction pattern of the deep trunk muscles, the transversus abdominus and lumbar multifidi with the aim of stabilising the lumbar segments. This method of muscle training is attractive because it has a theoretical basis. However, teaching isolated contraction of transversus abdominus and multifidi is not easy when patients have marked dysfunction of their muscles or are overweight. Adherence as with any exercise regimen can be a problem.⁴⁹

Physical fitness programmes

Physical fitness programmes aim to encourage patients with back pain to return to normal activities by means of graduated exercises, increasing endurance and

overcoming the fear of movement.⁵³ These programmes are generally supplemented by a cognitive behavioural approach to promote adherence and motivation. Exercises are carried out in group settings, with 3-10 people and patients are taught a programme of exercises aimed at:

- 1) Strengthening the main muscle groups in the body (including trunk and abdominal muscles).
- 2) Stretching the main muscle groups.
- 3) Increasing cardiovascular fitness with low impact aerobic exercises.

A simple and inexpensive fitness programme based on these principles was developed by the author in Oxford during the 1980's and termed 'Back to Fitness'.⁵³ The fitness programme includes similar components to the more intensive programmes that are termed multidisciplinary rehabilitation.

Multidisciplinary rehabilitation

The term multidisciplinary rehabilitation is used to describe programmes of exercise, physical fitness and education. Various programmes of rehabilitation have been developed which aim to focus on these factors but they vary in content and terminology. There are no guidelines defining the optimal rehabilitation programme but there is general consensus that management of patients with chronic low back pain should be multidisciplinary, and aim to restore normal function and behaviour.¹¹ Multidisciplinary programmes should include medical (pharmacological) treatment, advice, exercise, vocational and behavioural components and be provided by at least three health care professionals (e.g. physician, physiotherapist, psychologist, nurse or occupational therapist).²¹ Two

commonly used terms to describe these programmes are functional restoration and pain management.

Functional restoration programmes were originally developed by Mayer and colleagues in Dallas, USA. The focus was on promoting and maximising functional ability with or without pain.⁵⁴

Pain management programmes comprising exercise and education are based on a model of operant conditioning and involve positive re-enforcement of healthy behaviour.^{55 56} Cognitive treatment aiming to identify and change beliefs and thoughts about pain and disability are also advocated but there is no consensus about which psychological techniques are the most effective.^{57 58} Historically, these programmes have been delivered by multidisciplinary teams experienced in pain management. However they are expensive and modifications have evolved which reduce costs.^{59 60} Multidisciplinary programmes are recommended in the European guidelines for patients with chronic low back pain who have failed other conservative treatment.²¹

PASSIVE INTERVENTIONS

These techniques are carried out by the therapist and do not involve any active participation by the patient.

Manual therapy

Manual Therapy includes a wide range of joint mobilisation and manipulation techniques used by, osteopaths and chiropractors as well as physiotherapists. It also includes mobilisation of soft tissue. The term manipulation refers to a high velocity

thrust applied to the spinal joints at the end of joint range. Physiotherapists refer to this as Grade V manipulation in order to distinguish it from more gentle passive low velocity mobilisation graded from I to IV applied in various parts of the available joint range.⁶¹ Low velocity thrust techniques described by Maitland⁶¹ are most often used by physiotherapists.⁶² Manipulation is used infrequently by physiotherapists for the treatment of back pain probably because it is not taught at an undergraduate level.⁶²⁻⁶⁴

Soft tissue techniques

Soft tissue techniques include interventions that aim to mobilise soft tissue either by massage or passive stretching techniques. Massage techniques range from Swedish massage⁶⁵ to deep connective tissue massage and stretching of neural tissue.⁶⁶

Traction

Spinal traction is carried out both manually or using a motorised traction couch. The duration and magnitude of force can be varied and if motorised traction is applied it can be carried out continuously or intermittently. The rationale for the use of traction therapy is based on the mechanical effects of traction on the spine, mainly stretching structures. These mechanisms are thought to cause separation of the vertebrae, widening of the intervertebral foramina, movement of the facet joints, and stretching of spinal muscle and ligaments. The proposed mechanisms are not supported by research findings.⁶⁷

Electrotherapy

Transcutaneous electrical nerve stimulation (TENS), interferential therapy, ultrasound, short wave diathermy, laser therapy are all used by physiotherapist with the aim of providing pain relief. The theoretical basis for the use of these modalities is weak and they are not recommended in national or international guidelines^{21 68} However, they are taught as part of the curriculum at an undergraduate level and continue to be used in clinical practice.^{64 69 3}

Heat and cold (cryotherapy)

Cold treatment (cryotherapy) is generally recommended for acute injury within the first 48 hours of injury and heat is often used for chronic problems. The use of ice in the treatment of acute soft tissue injury is widespread but less frequently used for low back pain in the UK. The rationale behind the use of ice is the reduction of pain, swelling or muscle spasm with an associated decrease in metabolic rate of the underlying tissues.⁷⁰

Superficial heat methods convey heat by conduction (e.g. hot packs,) or convection (e.g. infra-red heat lamps). Deep heat is achieved by converting another form of energy to heat (e.g. shortwave diathermy). It aims to reduce pain and muscle spasm, and increase local circulation. There is limited evidence to support the use of heat for pain relief and reduction of muscle spasm and insufficient evidence to support the use of cold therapy.⁷¹

SURVEYS OF PHYSIOTHERAPY MANAGEMENT

The management of back pain by physiotherapists has been investigated in the UK, USA, Canada, the Netherlands and Thailand.^{62 72-75 76-78 79}

In a nationally representative sample of 1548 physiotherapist in Britain and Ireland (surveyed between 1994 and 1996) Maitland^{61 80} spinal mobilisation techniques (low velocity thrust grades 1-4) and the McKenzie approach to back pain were the most frequently reported treatments being used by 59% and 47% of physiotherapists respectively.^{81 61 80 62} Other treatments included electrotherapy (44%), abdominal (17.5%) and stretching exercises (15.3%). High velocity thrust techniques (manipulation), physical fitness programmes and multi-disciplinary rehabilitation were used infrequently. A more recent survey of 157 physiotherapists in Ireland⁶⁴ including 1062 patients reported similar findings suggesting that clinical practice has not changed significantly since 1996.

In Canada 274 physical therapists were surveyed and their views on management of low back pain were assessed. Patient education, exercise and electrotherapeutic modalities were the most common interventions for acute low back pain and exercise was preferred for sub-acute low back pain.⁷⁴ In the Netherlands 3148 physical therapy records were surveyed during 1989-1992 and 2002-2003. Exercise therapy was reported to be the most frequently applied intervention in 2002, while massage and electrotherapy modalities were the interventions of first choice in the early 1990s.⁷⁷ In contrast, the survey carried out on 502 therapists in Thailand reported a limited use of general exercise (27%) and the Mckenzie approach (15.7%) and high use of superficial heat (64.1%), ultrasound therapy (61.2%), and short wave

diathermy (28.5%).⁷⁸ In addition to the type of treatment the duration of treatment also varied between countries. The modal number of physiotherapy treatment sessions in Thailand was between 6 and 10 sessions (followed by 11-15 sessions) whilst the modal number of treatment sessions in Britain and Ireland was between 4 and 6 (followed by 7-10 sessions). Differences between and within countries are likely to be due to the patient profiles but also undergraduate and postgraduate training, health service resources and re-imbursement policies.⁷⁸

SUMMARY

The most commonly used physiotherapy techniques in the UK include various types of exercise regimes (in particular the McKenzie approach and spine stabilisation exercises) and manual therapy (low velocity joint mobilisation). Physical fitness programmes, joint manipulation (high velocity thrust) and multi-disciplinary rehabilitation programmes are less popular in the UK NHS.

By the early 1990's evidence suggested that traditional advice had little long term effect on back pain disability. A bio-psychosocial model of back care education was developed in the 1990's but there was no evidence that it was being used by physiotherapists.

Chapter 3

Evidence for physiotherapy management of back pain prior to implementation of the randomised controlled trial

SYNOPSIS

This chapter reviews the evidence for physiotherapy treatment prior to the development of the randomised controlled trial of low back pain which is presented in chapter four to six. It includes a description of methods used to appraise systematic reviews and randomised controlled trials that will be used throughout this thesis. The objective is to present a rationale for the implementation of the trial on the basis of a lack of strong evidence for physiotherapy management of back pain at the time (1996).

METHODOLOGICAL QUALITY OF TRIALS

During the mid 1990's two independent initiatives aimed at improving the quality of reports of randomised controlled trials (RCTs) led to the publication of the CONSORT (Consolidating Standards of Reporting Trials) statement. The CONSORT statement was developed by an international group of clinical trialists, statisticians epidemiologists and biomedical editors with the aim of improving the reporting of RCTs.⁸² The CONSORT statement includes a quality criteria check list and flow diagram and was intended for use in writing, reviewing or evaluation of RCTs. Most health care journals now reject research that does not adhere to the CONSORT statement but this was not the case prior to 1996.

The quality of trials reviewed in this thesis is based on assessment of internal and external validity. Internal validity is the extent to which systematic error or bias is minimised in a clinical trial.⁸³ External validity is the extent to which the results of a study provide an adequate basis for generalisation to other circumstances.⁸⁴ Factors such as the characteristics of the patients included in the trial, the setting, the treatment regimes tested and the modality of outcomes all affect external validity. In this thesis I have elected to use a scale developed by Jadad et al. (1996)⁸⁵ and adapted by Van Tulder et al. (2000)⁸⁶ for use in trials of physiotherapy and exercise because:

1. It assesses allocation non concealment which has been clearly shown to be associated with exaggerated treatment effects.⁸⁷
2. It is the only scale to be evaluated for discrimination, reliability and construct validity⁸⁸

The methodological criteria are described in Box 1.

	Methodological criteria
1	Was a method of randomization performed?
2	Was the treatment allocation concealed?
3	Was the withdrawal/drop out rate described?
4	Were co-interventions avoided or comparable?
5	Was the patient blinded to the intervention?
6	Was the outcome assessor blinded to the intervention?
7	Did the analysis include intention to treat?
8	Was the compliance acceptable in all groups?
9	Were the groups similar at baseline?
10	Was the care provider blinded to the intervention?
	The response categories were yes/no/unclear and 1 point was scored for each 'yes' response. The criteria for specific items are described in Appendix 9.

Box 1. Methodological criteria used to assess randomised controlled trials^{85 89}

A summary of trial quality for different interventions has been described by van Tulder (2003) using levels of evidence.⁹⁰ The levels of evidence are categorised as:

- Strong: consistent findings among multiple high quality RCTs.
- Moderate: consistent findings in one high level RCT and one or more low quality RCT or generally consistent findings in multiple low quality RCTs.
- Limited or conflicting evidence: only one RCT (high or low) or consistent findings in low quality trials.
- No evidence from trials or no RCTs.

High quality studies were defined as RCTs that fulfilled six or more of the validity criteria using Jadad's scale.^{85 89}

METHODOLOGICAL QUALITY OF SYSTEMATIC REVIEWS

A literature review aims to provide a concise summary of research evidence but bias can occur in the review process. A systematic review is defined as a study that has been prepared using a systematic approach to minimise bias and random error which is documented in a material and methods section.⁹¹ A review may or may not include a meta-analysis (a statistical analysis of the results from independent studies, which generally aims to produce a single estimate of a treatment effect).⁸³ More than 24 instruments have been developed to assess systematic reviews and the quality of these instruments varies.⁹² Cochrane reviews demonstrate higher methodological rigor and are frequently updated compared with reviews published in journals.⁹³

The QUORUM (Quality of reporting of meta-analysis) group was established in 1999 to standardise and improve reporting of systematic reviews. The group

produced the QUORUM statement with the aim of encouraging authors to provide adequate information regarding searches, selection, validity assessment, data abstraction, study characteristics, quantitative data synthesis, and trial flow.⁹⁴ A scale including several items recommended by the QUORUM group was developed by Oxman and Guyatt in 1991. It includes assessment of the search strategy, assessment of potential bias in the selection process, factors relating to the validity of included studies and validity of the conclusions. It meets several important criteria for assessment of systematic reviews (see Appendix 1). The scores range from 0 to 7 where 0-2 indicates extensive flaws and 7 minimal flaws. It was chosen for use in this thesis because the developers defined the construct they were interested in investigating, measured the discriminatory power of the items, and conducted inter observer reliability studies as part of the development criteria.⁹⁵

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IDENTIFICATION OF RELEVANT STUDIES

Reviews and randomised controlled trials including acute, sub-acute and chronic low back pain patients over the age of 18 were identified using the following databases; The Cochrane controlled trial register (CCTR), Ovid MEDLINE (1966 to 1996), EMBASE (1988 to 1996), CINAHL (1982 to 1996), PsycInfo (1985 to 1996) ISI web of Knowledge –Web of science; science citation index (Sci-expanded 1970-1996), PEDro (physiotherapy evidence database). The search strategy for reviews of physiotherapy intervention for back pain carried out using Ovid Medline is shown in Table 4. This strategy was adapted for EMBASE, PsycINFO and CINAHL.

A hand search of reference lists in relevant publications and reviews was carried out along with citation tracking using Web of Science and SCOPUS. Spine journal was searched from 1976 to 1996. The interventions were restricted to manual therapy (joint mobilisation and manipulation), electrotherapy, exercise, heat and cold, traction, backschools and advice intervention. Supervised group rehabilitation programmes that included a multidisciplinary behavioural approach were excluded from the review as they were rarely available in the NHS before 1996.⁵⁹ Reviews and trials that were primarily assessing spinal manipulation carried out by chiropractors or osteopaths were also excluded.

#	Search History	Results
1	back pain/ or low back pain/	18000
2	Backache/ or Spine/ or Low Back Pain/ or backschool\$.mp.	30368
3	backschool\$.mp.	5
4	exercise.mp. or EXERCISE/	142653
5	HEAT/	73451
6	musculoskeletal.mp.	22406
7	advice.mp.	16882
8	manipulation.mp.	34868
9	mobili\$.mp.	117229
10	physiotherapy.mp. or PHYSIOTHERAPY/	5946
11	Diathermy.mp.	2800
12	traction.mp.	11595
13	electrotherapy.mp. or Electrostimulation Therapy/	599
14	physical therapy.mp. or Physiotherapy/	22742
15	laser.mp.	95195
16	Ultrasound.mp.	83011
17	TNS.mp.	569
18	rehabilitation.mp.	68123
19	Systematic.mp.	62240
20	Meta-Analysis/	7390
21	"Review (Publication Type)"/	1265552
22	1 and 2	18000
23	or/3-18	659003
24	or/19-21	1317420
25	22 and 23 and 24	749
26	limit 25 to yr="1996"	46

Table 4. Search strategy for Ovid Medline 1966 to 1996.

REVIEWS OF PHYSIOTHERAPY MANAGEMENT FOR BACK PAIN

The search for reviews of physiotherapy intervention for back pain yielded 121 articles published in or prior to 1996 of which 17 fitted the criteria. The main reason for exclusion was the research was not a review or not a review of physiotherapy intervention (e.g. chiropractic manipulation, acupuncture, drug therapy or behavioural therapy). The search identified four reviews of backschools,^{45 97-99} four manual therapy/manipulation,¹⁰⁰⁻¹⁰³ two laser therapy,^{104 105} one TNS,¹⁰⁶ one, traction,¹⁰⁷ two of exercise^{108 109} and three general reviews of physiotherapy for back pain.¹¹⁰⁻¹¹² The reviews were carried out in the Netherlands, Denmark, USA, Canada and the UK and are summarized in Table 5-8.

The quality of the reviews varied with scores based on the Oxman and Guyatt⁹⁵ criteria ranging from two to seven and the most common methodological problem was the potential bias in the selection process.

Backschool intervention and manual therapy were reviewed extensively between 1992 and 1996 by authors in the UK, Canada USA and Netherlands possibly reflecting the popularity of this type of intervention at that time. The four reviews of backschools varied in quality but all authors concluded that the quality of the trials was poor.^{45 97-99} The highest quality review carried out by Cohen et al (1994)⁹⁷ suggested that there was insufficient evidence to recommend backschool education for patients with chronic low back pain.

Three out of the four manual therapy reviews either had major or extensive flaws.^{100 102 103} The authors of the lowest quality review published in 1992¹⁰⁰ concluded that there was clear evidence for manual therapy, particularly manipulative therapy

whilst authors of a higher quality review published two years later in 1996

¹⁰¹ concluded that the bias in interpretation of results in the trials they reviewed made the evidence inclusive.

Reviews of exercise were limited by the poor definition of exercise and the quality of the trials included. In a high quality review carried by Koes et al. (1991)¹⁰⁹ only trials of specific exercise were included and supervised physical fitness programmes, carried out in groups, were excluded. They used a scoring system from 0 to 100 to assess the quality of the trials. Only four trials¹¹³⁻¹¹⁶ out of 16 scored over 49 out of 100 points on the methodological quality scale indicating poor overall trial quality. Six studies found that exercise was better than a reference treatment¹¹⁶⁻¹²¹ and ten reported it to be no better or no worse than the reference treatment.^{113 115 122-128 129}

Studies that reported a positive effect of exercise were scored higher methodologically than the studies that demonstrated negative results lending some support to the use of exercise.

Trials of exercise were reviewed again in 1996 by Faas et al ¹⁰⁸ who included 11 randomised controlled trials published between 1991 and 1995. They identified four trials that assessed exercise therapy for acute pain,¹³⁰⁻¹³³ one sub-acute¹³⁴ and six trials of chronic low back pain.^{116 135-140} The review by Faas et al. (1996)¹⁰⁸ had major flaws due to the poor search strategy and potential bias caused by the poorly defined inclusion criteria. This review differed from the previous review ¹⁰⁹ as it included trials of more intensive physical fitness exercise. The authors attempted to define the types of exercise included but failed to note if the exercises were given in groups or individually and there were inaccuracies in the scoring of the trials.¹⁴¹ Two

trials investigating acute low back pain, with high methodological scores (>50),¹³²
¹⁴² reported no efficacy of flexion and extension exercise; two trials of McKenzie
exercises reported positive results but were low quality (<50).^{130 133} One trial
including sub-acute low back pain (> 50 points) reported positive effects of a graded
exercise programme and¹³⁴ three trials^{136 137 140} including patients with chronic low
back pain reported positive results with intensive exercise compared with low
intensity exercise but the evidence for long term benefits beyond 6 months was
weak. The quality of the trials had improved compared with the trials published
prior to 1991 but conclusions on the efficacy of exercise were still difficult to draw.
For sub-acute and chronic low back pain, physical fitness programmes and intensive
exercises had a more positive outcome.^{111 112}

One of the higher quality reviews of conservative treatment for low back pain
reported no strong evidence to support the effectiveness of any physiotherapy
intervention for acute low back pain.¹¹² However, for chronic low back pain van
Tulder et al (1996)¹¹² concluded that there was strong evidence for manipulative
therapy compared with placebo, moderate evidence that manipulative therapy was
more effective than usual GP care, bed rest, analgesics and massage and strong
evidence to support exercise therapy. No evidence was found that any specific type
of exercise was preferable. In contrast with other reviews, van Tulder et al.
(1996)¹¹² concluded that Backschools in an occupational setting were more effective
than usual care. All the other reviews of electrotherapy, TNS and traction concluded
that either the trials were of poor methodological quality resulting in inconclusive
findings or there was no evidence of effectiveness.^{105-107 110 112}

RANDOMISED CONTROLLED TRIALS OF PHYSIOTHERAPY MANAGEMENT

The review of randomised controlled trials in this thesis focused on manual therapy, education advice and exercise intervention for acute, sub-acute and chronic low back pain. It excluded trials that were primarily assessing manipulative therapy carried out by other practitioners. The search results are summarised in Appendix 2 and a description of the higher quality trials and reviews are detailed below.

Exercise for acute low back pain

A high quality Finnish trial ¹³² compared bed rest, back mobilising exercises instructed by a physiotherapist and advice given by a GP to continue normal activities (advice group) for 186 patients with acute low back pain. Patients were moderately disabled (Oswestry Disability Index =33%). At the 12 week follow up there was a significant difference in the ODI of 3.8% (95% confidence interval 0.1% to 7.5%) between the advice and bed rest groups and a significant difference of 2.6% (95% confidence interval -1.6% to 6.7%) between the advice and exercise groups in favour of advice group. This study suggests that continuing ordinary activities within the limits permitted by pain leads to a more rapid recovery than either bed rest or back mobilizing exercises. ¹³²

A similar high quality trial including 473 patients was carried out by Faas et al (1993). ¹³¹ The authors compared flexion and isometric abdominal exercises with placebo ultrasound and usual GP care. No positive effect of exercise was found over placebo ultrasound at one year although the exercise group had a shorter duration of pain. The exercises included in both trials were of very low intensity and based on four simple abdominal and lumbar spine mobility exercises. It was therefore

impossible to conclude from the studies by Faas et al. (1993)¹³¹ and Malminvaara et al. (1995)¹³² that all types of exercise were ineffective for acute low back pain.¹⁴¹

Exercise for sub-acute and chronic low back pain

In a high quality Danish study 105 patients with chronic low back pain were randomised to either an intensive dynamic back extension exercises programme, a similar less rigorous programme or traditional physiotherapy including massage, electrotherapy and mild exercises.¹¹⁶ Patients in the intensive exercise group gained most benefit at the long term follow up although during the first two to four weeks of treatment many patients in the exercise group experienced increased discomfort from muscles and continued back trouble. Improvements were not noted until the second and third month of treatment. The intensity and type of extension exercises that patients carried out in this study are not usually prescribed by physiotherapists in the UK.¹⁴³

Only one trial including 81 patients in the UK assessed physical fitness exercise for chronic low back pain. At six months patients randomised to a fitness programme were significantly improved compared with a control group who were taught exercises to do at home.^{140 144} This type of physical fitness exercise, supervised in groups, was not routinely available across the UK.⁶²

Manual therapy and combined physiotherapy intervention for sub-acute and chronic low back pain

A large multi-centre trial carried out prior to 1996 compared private chiropractic treatment including manipulative therapy with NHS hospital based physiotherapy

treatment and found physiotherapy to be less effective than chiropractic treatment.¹⁴⁵ The trial included 741 patients aged 18-65 with acute, sub-acute and chronic low back pain. Baseline disability scores were moderate (Oswestry Disability Index score; mean 28.5 SD 14.1 and 29.8 SD 14.2). This well conducted trial was criticised due to the bias introduced by the different treatment settings, the poor follow up rate, differences in the experience of the therapists and in contact time spent with the physiotherapists and chiropractors particularly during the long term follow up.¹⁴⁶ The chiropractic group had considerably more treatment over the long term and differences between groups were small at 6 weeks (mean difference in ODI 1.69 (95% confidence interval -0.74 to 4.12) but increased at the long term follow up (ODI means difference 3.18 (95% confidence interval 0.16 to 6.2) in favour of chiropractic treatment. This may have been due to the additional number of treatment sessions in the chiropractic group rather than specific benefits of the manipulative therapy. The size of the differences was small but the publication of this trial and media attention that it attracted caused considerable debate within the physiotherapy profession.¹⁴⁵

In a high quality trial of routine physiotherapy intervention carried out in the Netherlands,¹⁴⁷ the effectiveness of general practitioners management including advice about exercise, manual therapy, other forms of physiotherapy (electrotherapy, massage, heat and exercise) and placebo physiotherapy (detuned short-wave or ultrasound) were assessed. Two hundred and fifty six patients with sub-acute back and neck complaints were randomised. The main outcome was change in the severity of the main complaint. Follow up at 12 months was high (91%) and an

intention to treat analysis was included. Compared with general practitioners management and placebo, physiotherapy treatment was more beneficial in the long term but only small differences between groups were seen at the short term follow up. Many different types of physiotherapy were included, so it was impossible to draw conclusions about specific components of treatment.

Beurskens et al. (1995) compared high dose traction with sham traction for 151 patients with chronic low back pain and assessed global perceived benefit of treatment, pain and functional status. There was no difference between the groups in any of the outcome measures. This was the first high quality trial to provide evidence that traction was ineffective for patients with moderate low back pain. ⁶⁷

Brief educational intervention

There were no trials of brief educational intervention provided by a physiotherapist prior to 1996. Cherkin et al 1996 ¹⁴⁸ compared usual GP care with a back care booklet and concluded that a purely educational approach to back pain should be challenged. The booklet did not help to reduce disability, health care use or improve self-reported exercise and perceived knowledge in the long term.

Author	Inclusion criteria	Number of trials included	Intervention	Authors' conclusions	method score 0-7 scale†
Cohen et al 1994 ⁹⁷	Chronic low back pain	13 trials	Back school	There was insufficient evidence to recommend group backschool education for people with low back pain.	6 (minor flaws)
Turner 1996 ⁴⁵	Low Back pain	10 trials	Education and behavioural treatment (Backschool)	It may be useful to include cognitive behavioural treatment in backschools but more research is necessary to confirm.	4 (major flaws)
Koes et al 1994 ⁹⁹	Low back pain.	16 trials	Backschools	Most promising result were those modified from the Swedish back school and included more intensive treatment.	3 (major flaws)
Di Fabio et al (1995)	Chronic low back pain	19 trials including 2373 patients	Backschools	Calculation of pooled effect size data suggest that backschools alone were not substantially beyond control levels. Results were more positive when the backschool was combined with more intensive rehabilitation	3 (major flaws)

Table 5. Reviews of backschool intervention (prior to trial implementation) † (0 = extensive flaws; 7 = minimal flaws)

Author	Inclusion criteria	Number of trials included	Intervention	Authors' conclusions	method score 0-7 scale†
Beckerman et al 1992 ¹⁰⁴	General Musculoskeletal pain including back pain.	36 trials including 1704 patients	Laser	Small effects over and above placebo but low quality studies included and difficult to make firm conclusions	6 (minor flaws)
Gam et al 1993 ¹⁰⁵	General Musculoskeletal pain including back pain.	23 trial	Laser	NO evidence of an effect of laser treatment on pain	2 (extensive flaws)
Reeve et al 1996 ¹⁰⁶	Acute and chronic musculoskeletal pain including back pain and labour pain	35 trials	Transcutaneous electrical nerve stimulation (TENS)	Little evidence for TENS for back pain	6 (minor flaws)
van der Heijden 1995 ¹⁰⁷	Low back and neck pain	10 trials	Traction	No clear conclusions due to poor methodology and small sample size of RCTs included in the review.	6 (minor flaws)

Table 6. Reviews of electrotherapy, transcutaneous nerve stimulation (TNS) and traction intervention (prior to trial implementation)

† (0 = extensive flaws; 7 = minimal flaws)

Author	Inclusion criteria	Number of trials included	Intervention	Authors' conclusions	method score 0-7 scale†
Di Fabio et al 1992	Acute and chronic musculoskeletal problems including back pain	19 trials involving 2373 patients	Manual therapy	Authors concluded that there was clear evidence for manual therapy, particularly manipulative therapy for patients with less than 1 month duration of symptoms. This was a low quality review and the authors' conclusions may have been biased by methodology.	2 (extensive flaws)
Koes et al 1996 ¹⁰¹	Acute and chronic low back pain	36 trials	Manual therapy (manipulation)	The quality of the trials included was poor. There was bias in the interpretation and reporting of trials making the evidence inconclusive.	5 (minor flaws)
Koes et al 1991	Acute and chronic low back pain	35 trials	Manual therapy (manipulation)	No convincing evidence for manipulative therapy	4 (major flaws)
Shekelle et al 1992 ¹⁰³	Acute and chronic low back pain (included quantitative analysis)	25 trials	Manipulative therapy	Some evidence for acute LBP but data insufficient to advise on chronic low back pain	4 (major flaws)

Table 7. Reviews of manual therapy and manipulative therapy (prior to trial implementation)

† (0 = extensive flaws; 7 = minimal flaws)⁹⁵

Author	Inclusion criteria	Number of trials included	Intervention	Authors' conclusions	method score 0-7 scale†
Faas et al. 1996	Acute and chronic low back pain.	11 trials	Exercise including physical fitness programmes	Exercise for acute low back pain was ineffective. For sub-acute and chronic low back pain exercises including graded activity and more intensive exercise were considered to be more positive. No evidence for specific exercise.	3 (major flaws)
Koes et al 1991 ¹⁴⁹	Acute and chronic low back pain.	23 trials	Exercise excluding physical fitness programmes	Six studies found exercise was better than a reference treatment. 10 reported exercise to be no better or no worse than the reference treatment. Standard of the papers was poor. Studies that reported a positive effect of exercise were scored higher methodologically than the studies that demonstrated negative results.	6 (minor flaws)
Evans and Richards 1996 ¹¹¹	Acute and chronic low back pain	Acute LBP: Manual therapy= 23 Electrotherapy +TENS= 2 Exercise = 8 Back Schools = 2 Patient information booklet =1 Chronic LBP: Manual therapy =15 Exercise =9 Back school =8, TNS =5	Back schools, electrotherapy + TENS, exercise, joint mobilization and manipulation, and patient information booklet	Due to poor quality trials or no trials there was no evidence for electrotherapy. Weak evidence for physical fitness programmes, no evidence for specific exercise. Weak evidence for manipulative therapy for acute low back pain. No evidence for manipulative therapy for chronic LBP	4 (major flaws)

Beckerman et al 1993 ¹¹⁰	General Musculoskeletal pain including back pain.	400 trials including 1704 patients	Spinal manipulation or mobilisation, exercise therapy, traction, ultrasound, and laser therapy,	Overall poor quality studies and difficult to make firm conclusions for back pain interventions	2 (major flaws)
Van Tulder et al (1996) ¹¹²	Acute + chronic low back pain	Acute LBP Exercise = 10 Back School = 4 Manipulation=16 TENS =2 Chronic LBP Exercise =16 Back School = 10 Manipulation =9 TENS =3 Traction =1	Spinal manipulation or mobilisation, exercise therapy, traction, TENS, Back School	Acute LBP : Overall poor methodological design resulting in no strong evidence to support the effectiveness of any intervention Chronic LBP: Strong evidence that manipulation was more effective than placebo. Moderate evidence that manipulation was more effective than usual GP care, bed-rest, analgesics and massage. Strong evidence for exercise therapy and moderate evidence that the various exercises were equally effective. Strong evidence that Backschools in occupational settings were more effective than usual care. NO evidence for TENS or traction.	6 minor flaws

Table 8. Reviews of physiotherapy interventions including exercise (prior to trial implementation)

† (0 = extensive flaws; 7 = minimal flaws)⁹⁵

DISCUSSION

Systematic reviews aim to make robust estimates of effectiveness over a series of studies and solve conflicting results of randomised controlled trials. Prior to 1996, when methods of quality assessment were not standardised and overall quality of trials was poor, this was not possible. Jadad et al (1997) recommend basing conclusions on reviews that have few or minimal flaws and the development of the trial protocol, described in chapter four, followed this recommendation.¹⁵⁰

The quality of trials and reviews varied reflecting the lack of standards set latterly by the QUORUM group and CONSORT statement.^{92 94 151} Reviews depend heavily on the expertise and experience of the researchers and mistakes in the scoring of trials in some reviews suggested that bias in the assessment process was possible.^{141 152}

Some reviews included very small trials and few were able to pool data due to the heterogeneous trials included in the reviews.

Disadvantage of the methodological scoring system

The methodological rating scale for assessment of quality of trials used in this thesis does not take into account small sample sizes or the validity of the outcome measures. The score assignment is equally weighted for each of the 10 points but a trial could theoretically be scored high on the scale but have a very poor follow up rate that would be important to the validity of the trial. Additionally, the scale is heavily weighted towards blinding of care providers and patients that is not always possible in trials of physiotherapy intervention.

The methodological scales for the trials and the reviews focus on internal validity and ignore aspects of external validity such as the quality of intervention and clinical setting. Most of the reviews concentrated on describing the attributes of the trials and few described the interventions clearly. The reviews enabled the reader to appreciate that the intervention was or was not effective, but left them unclear as to what exactly the intervention included. The methodological problems of systematic reviews are discussed in more detail in chapter 10.

Efficacy of physiotherapy intervention

Most of the reviews of physiotherapy intervention for back pain were inconclusive due to methodological problems in the reviews and trials. Only five out of the 15 reviews scored six on the quality scale indicating minimal flaws. None of the reviews provided clear guidelines for physiotherapy management and most of the higher quality reviews concluded that there was insufficient evidence to support the intervention. Reviews of high methodological quality generally present more negative and uncertain conclusions than those of low quality and this was evident in the literature at that time.¹⁵³

There was no evidence to either support or refute the use of specific exercise, such as McKenzie or spine stabilisation exercises, for acute or chronic low back pain in spite of the popularity of these exercises amongst physiotherapists in the UK.^{108 149}

Van Tulder et al (1995) recommended exercise therapy for chronic low back pain but did not provide any information on the type and intensity.¹⁰⁸

There was moderate evidence that mechanical traction was ineffective for sub-acute and chronic low back pain^{67 154} and no evidence to support the use of electrotherapy for acute or chronic low back pain.^{3 108} There were slightly conflicting conclusions from the four backschool reviews but the highest quality review, with minimal flaws, concluded that there was insufficient evidence to recommend group backschool education. Lack of evidence for these interventions was a defining factor in the development of the trial protocol described in chapter four.

There was weak evidence, from one high quality randomised controlled trial, suggesting that any potential impact of physiotherapy including manual therapy may be explained by placebo effects.¹⁴⁷ A placebo effect occurs when patients feel effects from treatment when no active treatment has been given. The placebo effect is complex and influenced by patient expectations, health care communication skills and interaction.¹⁵⁵ Very few trials of physiotherapy for back pain include a true placebo group.

Overall, there was no strong evidence to support routine physiotherapy intervention per se for treatment of back pain.

Chapter 4

Rationale and development of the trial protocol

SYNOPSIS

This chapter describes the background and development of a randomised controlled trial that was instigated as a result of NHS purchasers requesting evidence for physiotherapy management of low back pain. It reports the clinical guidelines for the management of low back pain prior to 1996 that recommended evaluation of the effectiveness of physiotherapy management in primary care as a priority.

FACTORS THAT INFLUENCED THE TRIAL DEVELOPMENT

Guidelines for management of low back pain prior to 1996

In 1994 the Clinical Standards Advisory Group (CSAG) published a report on back pain with a remit to consider the literature and offer advice to UK health service clinicians.¹⁵⁶ The CSAG report suggested that evaluation of the effectiveness of physiotherapy treatments used in primary care was one of the highest research priorities. In 1996 guidelines were produced by the Royal College of General practitioners.¹⁵⁷ The guidelines recommended offering patients advice to stay active, considering spinal manipulation for acute low back pain, non specific exercise therapy and multi-disciplinary rehabilitation for chronic low back pain. However, the evidence to support the guidelines was weak and there is little to suggest that the guidelines influenced physiotherapy practice at that time.¹⁵⁸

A challenge for physiotherapy service provision in Oxfordshire

The large UK trial that compared chiropractic treatment in a private setting with physiotherapy within the NHS¹⁴⁵ caused considerable debate amongst physiotherapists, chiropractors, NHS managers and purchasers. It challenged the role of physiotherapists within the NHS as the main providers of treatment for back pain. The trial raised levels of awareness amongst clinicians and managers of the need to provide evidence for physiotherapy intervention.

Description of recruitment of the trial centres

In 1995 managers of the Oxfordshire Physiotherapy Services were challenged in the Health Authorities Priority's Forum to provide some evidence that the service they offered people with back pain was effective. Following discussion with service providers, managers and researchers a plan was developed to write a research protocol with the aim of providing evidence for physiotherapy practice in Oxfordshire. A trial management group was established by the Director of Physiotherapy Research (chief investigator), Nuffield Orthopaedic Centre NHS Trust and the Director of Health Services Research Unit (Sarah Stewart-Brown), University of Oxford that included clinicians and managers. A proposal of research was circulated to the five managers of the Oxfordshire teaching and community hospitals. The physiotherapy managers agreed to support the study (See Appendix 3) and nominated senior clinicians to attend initial collaborators meetings. During 1994-1995 over 3000 new patients were treated by physiotherapists in the Oxfordshire County; this accounted for the majority of physiotherapy out-patient visits but included those with specific and non-specific mild and severe back pain.

In 1996 most of the physiotherapy departments took general practitioner referrals but as they were located in secondary care self referral to physiotherapy was not accepted. The centres included physiotherapy departments in the following hospitals or centres;

- Nuffield Orthopaedic Centre NHS Trust. This was a large physiotherapy outpatient department employing approximately five whole time equivalent physiotherapists within a specialist university teaching hospital located in Oxford. All patients were referred to the consultants and then to the physiotherapy departments. During the recruitment phase a physiotherapy triage clinic was established and referrals were then directed from the orthopaedic surgeons and rheumatologists directly to the physiotherapists in the triage clinic.
- Churchill hospital NHS Trust and Radcliffe Infirmary NHS Trust. These were large physiotherapy outpatient department (employing 7.5 whole time equivalent physiotherapists) within teaching hospitals that took direct referrals from general practitioners and consultants in Oxford.
- Wallingford Community Hospital, Abingdon Community Hospital and Witney Community Hospital. These were smaller physiotherapy departments (employing 2.5 to 3 whole time equivalent physiotherapists in each department) in community hospitals located within 25 miles of Oxford. Referrals were from general practitioners and consultants,
- Horton General Hospital, Banbury, Oxfordshire. This was a large physiotherapy department employing four whole time equivalent

physiotherapists in a District General Hospital located in Banbury taking referrals from general practitioners and consultants. This centre did not recruit patients in the first eight months of trial recruitment due to staffing difficulties. In addition, it was difficult to find a designated trial research therapist in that area.

- Brookside Medical Centre, Reading. A small physiotherapy department employing two whole time equivalent physiotherapists in a general practice medical centre located in Reading. Referrals to physiotherapy were from general practitioners only. This centre was included latterly due to one of the original collaborating centres (Witney Community Hospital) being unable to recruit a trial research therapist. The chief investigator visited this centre to introduce the trial to the general practitioners and physiotherapists in that centre and following agreement from the practice manager, general practitioners and physiotherapists, ethical approval was applied for and approval given. A trial research therapist was employed and trained by the chief investigator along with any clinicians involved in the trial.

Rationale for a randomised controlled trial

During development of the protocol the trial management group considered important clinical and research issues. Study methodology was discussed and whilst it was acknowledged that observational studies were useful for evaluation of treatment particularly in cases where the condition under investigation are rare ¹⁵⁹ it was recognised that a randomised controlled trial was the most powerful tool for evaluating effectiveness of treatment for back pain. The randomisation process was

an effective way to reduce allocation bias in selecting treatment because it guaranteed that treatment would be assigned by chance. It prevents the investigator from consciously or unconsciously allocating treatment on the basis of patients' attributes which could influence the outcome. Allocation bias can influence trial outcomes as strongly as treatment effects and it was therefore an important factor to consider in trial design.¹⁶⁰

Advantages and disadvantages of multi-centre trials

Advantages

- Multi-centre trials increase the potential pool of patients. This helps to ensure that an adequate number of subjects are recruited reducing the risk of a type 2 error occurring.¹⁶¹
- Multi-centre trials increase the likelihood that the study population is representative of the broader population of back pain and this supports the external validity of the trial.
- Multi-centre trials enable clinicians who have not previously been involved in research to participate thereby introducing research skills to those working in smaller departments as well as those in teaching hospitals.

Disadvantage

The disadvantages were that administration and organisation of data collection was more challenging. It was essential that all collaborators were motivated and remained so throughout the trial in order to maximise trial success.

Trial organisation

The trial was designed to run from the lead centre and funds were allocated for a trial administrator to collect data and collaborate with all members of the team. To overcome the disadvantage of not having the trial management team on site regular meetings were held with the team to motivate staff in the collaborating centres and reinforce the importance of following the trial protocol. The trial administrator and chief investigator were easily contactable over the telephone to deal with any issues that arose on a daily basis.

The role of the trial administrator

The part-time trial administrator was interviewed and recruited by the grant holders. The role of the trial administrator was to liaise with the trial research therapists and clinicians, type documents, mail follow up questionnaires, collect and enter trial data, and assist the chief investigator in the organisation of collaborators meetings.

Description of recruitment of trial research therapists

A job description for the trial research therapists was distributed to the managers at the collaborating centres. Funding was available for a senior 1 physiotherapist for four hours per week. Managers identified physiotherapists who were interested in the post and they were all interviewed by the chief investigator. Where there were no suitable candidates already working within a department, research physiotherapists were recruited by local advertisements and employed to recruit patients in more than one centre. Throughout the trial one research therapist was employed for 12 hours a week to recruit patients from the Nuffield Orthopaedic centre, Churchill Hospital and Radcliffe Infirmary. In all the other centres a

physiotherapist already working in the department was employed to recruit patients and the department was reimbursed for the hours worked.

Training of trial research therapists and clinicians

All trial research therapists and clinicians involved in the early phase of the trial were trained at collaborators meetings where the protocol was explained in detail. Meetings were held at the Nuffield Orthopaedic Centre where training was given by the chief investigator. In addition the chief investigator and the trial administrator visited centres individually to explain the trial protocol and standardised procedures to all clinicians involved in the trial. Role play was carried out at the collaborators meetings to ensure that the trial research therapists followed a standardised procedure and that they felt confident in their role of recruiting and consenting patients. The trial research therapists were given documents including the trial protocol, guidelines and instructions for recruitment, a check list for initial contact including the selection criteria, patient and general practitioner letters, patient information sheets and general practitioner summary sheets, consent forms (Appendix 4), standardised questionnaires (Appendix 5), assessment forms and patient diaries (Appendix 6), sealed, opaque randomisation envelopes, guidelines and information sheet for physiotherapy clinicians, back care booklets (The Back Book)⁴⁷ and a questionnaire for the physiotherapy clinicians to complete when all treatment was completed (Appendix 7). An information pack containing the trial protocol and procedures was readily available in each department and the trial research therapists were trained to advise clinicians about the treatment protocols. When new staff joined, the trial research therapists informed the chief investigator

and if the new clinicians were unable to attend collaborators meetings the chief investigator visited the centres to ensure that the protocol was followed.

The trial was pragmatic and clinicians were able to treat patients using pre-acquired skills within the limits of the protocol (i.e. no traction or electrotherapy). No additional clinical training was given as the protocol aimed to assess routine treatment. However, all therapist were asked to read through 'The Back Book' with the patients in the advice only group and discuss any issues arising from it.

Development of the trial intervention

The chief investigator held meetings with clinicians in the collaborating centres to discuss the nature of the intervention. The physiotherapists wanted to maintain clinical autonomy and deliver treatment that was widely practiced. The following issues were considered:

- The different classification and assessment methods used by physiotherapists: The trial aimed to assess current practice within the NHS and it was therefore important that a range of the most commonly practiced assessment paradigms would be permissible as long as red flag indicators¹² were used initially to exclude serious pathology. This pragmatic approach was necessary to encompass variation in physiotherapy classification and assessment of non-specific low back.^{14 162}
- The weakness of the evidence base to support the use of most physiotherapy intervention for patients with back pain:^{3 14 101 102 109 145 162 163} The relevant literature was discussed but it was difficult to draw firm conclusions about best practice. While it was recognised that some standardisation of the

intervention was necessary, it was agreed to adopt a pragmatic approach to intervention allowing for clinical autonomy. Some interventions such as laser, shortwave, transcutaneous electrical nerve stimulation (TENS) or ultrasound were excluded due to lack of evidence to support their use and because the methods were not widely used by clinicians in the collaborating centres.

- Clinical guidelines did not specify particular exercise regimes for low back pain so the trial protocol reflected routine clinical practice allowing for any type of individually taught exercise.
- There was no evidence for brief educational intervention alone for patients with chronic low back pain. During the early 1990's the Back Book was developed by a multi-disciplinary group of back pain experts with the aim of shifting the emphasis from the traditional medical model of back education to a bio-psychosocial approach that takes into account psychological and social factors.⁴⁷ The Back Book was written in conjunction with the UK RCGP guidelines⁶⁸ and was beginning to be used in clinical practice.¹² Preliminary studies showed that it was accepted by patients who understood its messages and that it created a positive shift in beliefs about low back pain.¹⁶⁴ The Back Book⁴⁷ was a novel, promising initiative that had not previously been included in a trial of physiotherapy for back pain.¹⁶⁴ It was agreed that 'The Back Book' would be distributed to both groups as the main aim of the trial was to assess benefits of physiotherapy techniques in addition to advice.

Rationale for treatment intensity

Physiotherapy group

The maximum number of treatment sessions offered to patients in the trial was based on a local audit that suggested that six treatment sessions was the average. This was in line with evidence from a survey of physiotherapy management in Great Britain and Ireland.⁶² The protocol therefore allowed up to six sessions with the potential to offer additional sessions if the clinician considered it necessary (this was not encouraged). It was not necessary to carry out any pilot work to check the feasibility of the intervention as it included routine practice.

Control group

A non intervention group was considered as a control group but as the patients were already referred for physiotherapy, without prior notice of the trial it would have made recruitment particularly difficult.

A placebo group was also considered and the rationale to exclude a placebo group is discussed later in this chapter.

In 1996 it was uncommon for physiotherapists to offer a one off treatment of advice for patients with back pain but it was agreed that this approach would be implemented in the trial as the control intervention. Some clinicians were already using this approach and were happy to offer advice only as treatment. Inclusion of prescribed exercise was discussed but the clinicians would not agree to teach exercises without a second follow up appointment. The clinicians believed it was important to check exercises to ensure they were being carried out properly and

without a second follow up appointment there was a potential risk that the exercise could cause more harm than benefit. Therefore physical activity advice was offered but no exercises were taught.

Protocol violation

Physiotherapists who agreed to participate in the trial were concerned about how to deal with non compliers, deteriorating patients or patients who requested further treatment following randomisation. These are common problems for any trial.¹⁶⁵

Protocol violation was discussed with the physiotherapy clinician and deviation from the protocol was discouraged but it was recognised as inevitable that some patients would request more treatment. The aim was to avoid patients returning to their general practitioner for help and creating additional work in primary care. The protocol specified that for patients who requested further treatment the physiotherapist would use his/her clinical judgment to decide if further treatment was necessary.

Choice of instruments for the trial

The instruments used to assess patients in the trial were chosen because they had been shown to be reliable, valid and responsive in groups of patients with low back pain and therefore it was not considered necessary to carry out a pilot study to check the feasibility of each instrument.¹⁶⁶⁻¹⁶⁹ In addition the chief investigator had successfully used the Oswestry Disability Index in a previous trial of a similar group of patients with chronic low back.^{140 144} The Oswestry Disability Index (ODI) was chosen as the primary outcome because data was available to calculate the power of

the study and it had been shown to be a valid, responsive and reliable measure.^{166 168} The Roland and Morris Disability Questionnaires (RMDQ) was included as a secondary measure as it was expected that patients with a range of disability would be recruited and previous research suggested that the two outcomes were complimentary.¹⁶⁶ A generic measure (SF-36) was included to capture a broader measure of the patient's general health. Research suggested that the Patient Specific Activity Questionnaire was more sensitive to change than the ODI and RMDQ and it was therefore included as a secondary measure along with the SF-36.¹⁷⁰ The length and complexity of the questions was considered important and additional questionnaires were excluded on the grounds that they might over-burden the patients. Soon after the protocol had been written a standardised set of outcome measures, including those chosen for this trial, were recommended by a group of international back pain experts¹⁷¹ confirming that the choice was justified.

Feasibility of trial protocol

The feasibility of the trial protocol was assessed at the Nuffield Orthopaedic Centre where the chief investigator and clinicians had previous experience of implementing randomised controlled trials.^{140 144 172 173} A trial research therapist was employed to recruit patients at the Nuffield Orthopaedic Centre, Churchill General Hospital and Radcliffe Infirmary following a standard procedure. No problems with the protocol arose and recruitment within the first six months was within target. Recruitment slowed down considerably over the following six months due to clinical staff shortages in some centres resulting in longer waiting times for patients to be treated. One of the centres (Witney Community hospital) was unable to provide a trial

research therapist and the Brookside Practice in Reading was approached to help boost recruitment levels. The Horton District Hospital also had staffing problems and it was impossible to recruit a trial research therapist at that centre in the first eight months of the trial recruitment phase.

Method of recruitment

The possibility of approaching all general practitioners in the area with the aim of recruiting patients directly from primary care was considered. This would have had the advantage that patients would be fully informed about the trial prior to referral and there would be no expectations about treatment intervention from the patient's general practitioner. However, this method of recruitment would have made the project more expensive and logistically more difficult. Recruiting patients directly from the physiotherapy departments in primary and secondary care meant that only the general practitioners who referred patients for physiotherapy would receive information about the trial. This method had the advantage that the population recruited would reflect normal referral and practice.

Intention to treat analysis

The importance of using an intention to treat analysis¹⁶⁵ was explained to the clinicians during the training sessions. Intention to treat (ITT) is a strategy for the analysis of randomised controlled trials that compares patients in the groups to which they were originally randomised.¹⁷⁴ Intention to treat analysis has two main purposes:

1. The approach maintains treatment groups that are similar apart from random variation
2. It allows for non-compliance

An intention to treat analysis is essential in the analysis of a pragmatic trial because it gives an estimate of the benefits of a change in treatment policy rather than of benefits in patients who receive treatment exactly as planned.¹⁷⁴

Concern was expressed about this approach as some physiotherapists thought that patients would not be happy with minimal intervention and consequently that many patients would request further treatment and violate the protocol. It was explained that this would be considered in the interpretation of the results but the principle method of analysis would be intention to treat.

Trial blinding

Blinding of treatment

Blinding of treatment from the patient, the clinicians and trial investigators is important in preventing bias. Patient's knowledge of treatment can cause psychological benefits particularly if they believe they are receiving a superior treatment and the reverse psychological effects can occur if they believe they are receiving inferior treatment. The clinician's knowledge of treatment can also influence their enthusiasm for treatment and potentially cause bias.¹⁶¹

Blinding of patients and clinicians

Blinding of patients and clinicians was impossible for ethical and practical reasons as patients were fully informed of the possible treatment options and therefore knew

which treatment they were receiving. There was no possibility of blinding the clinicians to treatment allocation for practical reasons. It would only be possible to blind clinicians to physiotherapy intervention in trials where no difference in sensation or input of treatment occurs or where equipment used in the intervention can be adapted.¹⁷³

Blinding of investigators

To avoid assessment bias importance was placed on blinding the assessor, data processor and data analyst. The treatment allocation was coded so that data handling was blind to treatment allocation until after the analysis. The initial assessment was carried out before randomisation and treatment allocation and follow up data was collected by post. The trial was therefore investigator blind.

Ethical considerations

Where there is uncertainty regarding treatment efficacy, clinical trials are justified and many would say necessary.¹⁶⁰ In 1996 many physiotherapy interventions were based on weak evidence, opinion and beliefs without the benefit of rigorous scientific support.¹⁷⁵ Clinicians have an ethical obligation to acknowledge uncertainty and take steps to address the discordance between evidence and practice. The clinicians agreed generally with this but were keen to provide evidence to support their interventions. Clinical equipoise, a state of genuine uncertainty on the part of the clinician regarding the comparative therapeutic merits of each arm in a trial,¹⁷⁶ was a difficult concept for many working in clinical practice and this issue is discussed further in chapter ten.

Ethical issues of placebo treatment as a control group

An initial protocol was developed and submitted to the Oxfordshire Locally Organised Research Scheme in 1995 that included de-tuned pulsed short wave as a placebo control arm of the study. This application was rejected by the funding body on the grounds that the trial could not be implemented. One of the reasons for rejection was the referees' perception that the placebo arm of the trial was unethical. Physiotherapy trials (n=10 between 1979-1995) had included placebo treatment to evaluate the effectiveness of physiotherapy techniques prior to this application.³ Placebo treatment (20 minutes placebo ultrasound) had previously been shown to be no different to physiotherapy (flexion and abdominal exercises) in terms of number and duration of back pain recurrences in patients with acute low back pain.¹³¹ It could be argued that it was unethical to offer treatment that was not evidence based, but the protocol design was changed on the basis of these early comments. Following discussion with the trial management group the placebo group was dropped from the protocol mainly to help recruitment. An initial grant was awarded for the project in 1996 and a second follow up application was supported by the Arthritis Research Campaign in 2000 at a total cost of £86454.

SUMMARY

A protocol for a randomised controlled trial was developed with the aim of evaluating physiotherapy intervention for non-specific, sub-acute and chronic back pain that would reflect current practice within the NHS.

The protocol took into account evidence from randomised controlled trials and reviews, clinical consensus and locally available physiotherapy services for patients with non-specific back pain.

Various issues arose during the developmental phase of the trial including the challenges of standardisation of research protocols. Clinical equipoise was particularly challenging to therapists with no experience of involvement in randomised controlled trials.

Chapter 5

Trial methods

SYNOPSIS

This chapter includes the trial hypothesis, describes the methodology of the multi-centre randomised controlled trial, the process of recruitment treatment of patients and the rationale behind the choice of instruments used to assess clinical outcome.

TRIAL OBJECTIVE AND HYPOTHESIS

Objective

The objective was to investigate the effectiveness of physiotherapy treatment, as commonly practiced in the UK NHS, compared with a single session of assessment and advice, delivered by a physiotherapist, in promoting recovery from low back pain.

Primary hypothesis

Experimental hypothesis

Patients with sub-acute and chronic low back pain who attend routine physiotherapy treatment will report significantly less disability over one year, compared with patients who are given a back care booklet and attend a single session of self-management advice given by a physiotherapist.

Null hypothesis

There will be no difference in reported disability over one year between patients with sub-acute and chronic low back pain, who attend for routine physiotherapy

treatment compared with patients who are given a back care booklet and attend a single session of self-management advice given by a physiotherapist.

STUDY DESIGN

The study design was a multi-centre, investigator blind, randomised controlled trial.

PROCEDURE

Seven physiotherapy departments based in NHS hospital outpatient departments agreed to take part in the trial. The principle investigator (Helen Frost) visited each centre individually and organised collaborator meetings to explain the trial protocol and maintain motivation. Figure 1 shows the flow of participants through the trial.

ETHICAL APPROVAL

Ethical approval was granted from the Nursing and Allied Professions Research Ethics Committee (no. 1237) and the West Berkshire Local Ethics Committee (no 80/99).

ELIGIBILITY CRITERIA

Inclusion criteria

Eighteen years of age and over with at least a six week history of low back pain with or without leg pain or neurological signs.

Exclusion criteria

Serious pathologies including systemic rheumatological disease, gynaecological problems, ankylosing spondylitis, tumours, infection, past spinal operations, pregnancy, serious spinal pathology (cauda equine symptoms) unable or unwilling to

complete questionnaires independently and physical therapies in the last month.

Patients referred for intensive functional restoration programmes were also excluded as they had more complex back problems. These patients were also more likely to have had previous routine physiotherapy that may have shaped their beliefs about treatment outcome.

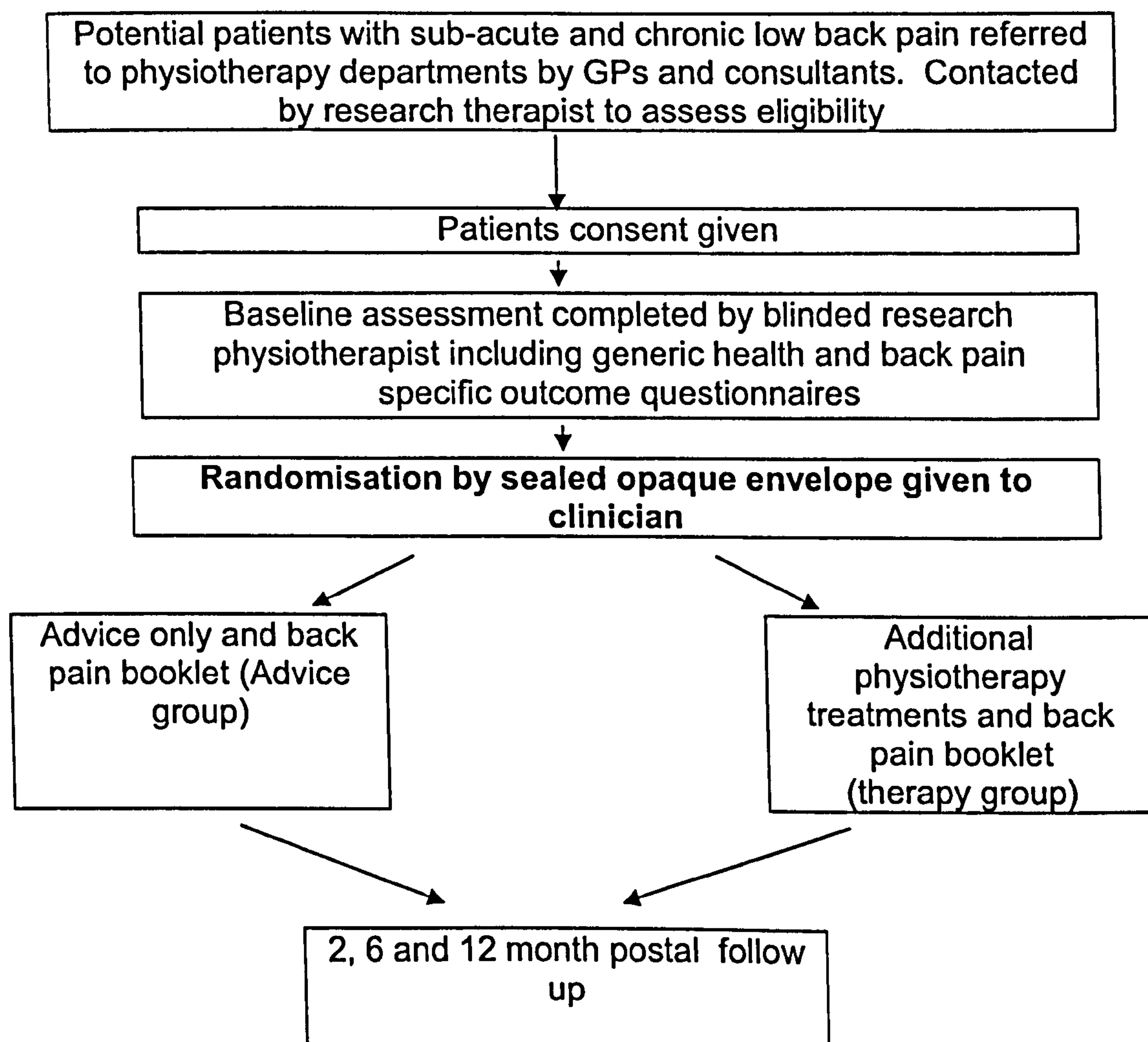


Figure 1. Flow of participants through the trial

OUTCOME MEASURES

Subjective outcome measures for back pain fall into three categories: disease specific (measures designed specifically to assess common problems associated with back pain), generic health measures (measure that assess general health across different diseases) and patient specific measures (measures that assess patient specified problems that are directly related to the individual). These measures will be discussed further in chapter eight.

Primary outcome measure

Oswestry Disability Index (ODI) at 12 months

The Oswestry Disability Index is a disease specific measure developed specifically for assessment of back pain and is recommended as one of the principal outcome measures for trials of the management of spinal disorders.^{177 178} It has ten dimensions: pain intensity, personal care (washing dressing etc.), lifting, walking, sitting, standing, sleeping, sex life (if applicable), social life and traveling. Each dimension has six levels, with a score of zero allocated to the least disabled level and a score of five allocated to the most disabled level. The total score is converted to a percentage with a consequent maximum of 100%. The validity and responsiveness of the questionnaire has been assessed in various groups of back pain patients.¹⁷⁹⁻¹⁸¹ The minimum clinically significant change in the Oswestry Disability Index has been estimated by different observers as being somewhere between 4 and 17, which relates to a change in score for an individual patient or a change in mean score for a group of patients (See Appendix 5).

Secondary outcome measures

The Oswestry Disability Index (ODI) at 2 and 6 months. ^{168 178 180}

The Original Roland and Morris low back pain disability questionnaire

(RMDQ). This questionnaire is a disease specific measure, adapted from the

Sickness Impact Profile ^{169 182 183} designed to assess physical disability due to low

back pain. It includes 24 items relating to physical function. There is no consensus

on what is an important clinical change but 2-3 points have been documented as the minimum. ¹⁸⁴ (See Appendix 5)

Both the ODI and the RMDQ were included as research suggested that they were complimentary when assessing a broad range of disability. ¹⁸⁵⁻¹⁸⁷ We were expecting to recruit patients with a range of disability and therefore we included both measures. The ODI was chosen as the primary outcome as we had data available from a previous trial ¹⁴⁰ of patients, from a similar population, that could be used to estimate the sample size.

The Short Form 36 (SF-36). The short form 36 health survey (SF-36) is a 36 item generic questionnaire that was constructed in the U.S.A to represent eight important health concepts. ¹⁸⁸ The United Kingdom version of the SF-36 is based on work by

Brazier et al. (1992), Garrett et al (1993) and Jenkinson et al (1993). ^{167 189-191} It

measures function on eight dimensions (general health perception, physical

functioning, role (physical), role (emotional), pain, social functioning, mental health,

energy/vitality). For each of the eight dimensions, item scores are coded, summed

and transformed to a scale of 0 (worst possible health state) to 100 (best). The

coding for the UK SF-36 version was used. ¹⁸⁸ The SF-36 can be scored as two

summary scales: physical component score (PCS) and the mental health component score (MCS). (See Appendix 5)

It was well validated at the time the protocol was developed and had the advantage of covering all aspects of emotional and physical well being.^{189 192 193} It is recommended as one of a core set of measures for assessment of back pain and the best generic measure in terms of length, reliability validity, responsiveness and experience in large populations of patients with back pain. It also includes a bodily pain scale that provides a measure of pain intensity and pain interference with activities.¹⁷⁷

Patient Specific Activity Questionnaire. Common activities of daily living such as walking and sitting, that are include in back pain specific questionnaires, are important to most patients. For some patients, other activities not included in the back pain specific questionnaires, may be more important and the reason that patients seek health care intervention. An example of this is the sportsperson who gets back pain after running 1 km on uneven ground or the avid gardener who finds digging difficult because of back pain. Changes in these main complaints may not be detected on disease specific or generic measures but are important to patients. The patient specific approach has been evaluated in other areas of health such as ankylosing spondylitis¹⁹⁴ as well as back pain.¹⁷⁰ The main patient complaint was selected using a standard format. Patients were asked what activity they perceived to be important and which was difficult to perform because of their back pain in the previous week. A list of 36 activities was offered as suggestions to support recall but they were also allowed to choose activities that were not on the list. (See

Appendix 5) They were not encouraged to select activities that they could avoid.

The difficulty of the activity was measured on a 0-10 visual analogue scale (0 = no problem with activity, 10 = impossible to carry out activity). This questionnaire was included as it was found to be as responsive as other specific back pain questionnaire but additionally it was thought that it may detect changes on symptoms that are highly relevant to individual patients.¹⁷⁰

Global patient perceived benefit This was measured by the patients at two, six and 12 months post randomisation on a categorical scale (yes or no response) and numerical analogue scale 0-10 scale (0=no perceived benefit of treatment , 10=maximum benefit of treatment). At 12 months post randomisation they were asked if they felt their back pain was better, the same or worse following the treatment they received.

A summary of the instruments properties are described in Table 9. Additional information including resource use data, work loss, smoking habits and activity levels were also recorded.

Instrument	Dimensions	Measurement
Oswestry Disability Index ¹⁶⁸	Pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, sex life (optional) and traveling.	0% (best health state) to 100% (worst health state)
Roland and Morris Disability questionnaire ¹⁶⁹	24 statements about different aspects of daily living	0 (best health state) to 24 (worst health state)
SF-36 ¹⁶⁷	General health perception, physical functioning, role physical, role emotional, pain, social functioning, mental health and energy/vitality	0 (worst health state) to 100 (best health state)
Patient Specific Activity questionnaire ¹⁷⁰	Patient specific activities affected by back pain in the last week. e.g. sitting, walking, bending, driving, standing, sport, lifting, running	0-10 visual analogue scale (difficulty of main complaint)
Global patient perceived benefit	How much benefit perceived from treatment	0-10 numerical scale (0 = no benefit, 100 = maximum benefit)

Table 9. Summary of the outcome instruments used in the trial.

PROCESS OF RECRUITMENT AND TREATMENT OF PATIENTS

Part-time trial research therapists were employed in each of the seven centres to identify potentially eligible patients and to make contact with them. The process of recruitment was as follows;

1. The trial research therapist identified any potential referrals from the waiting list at their designated centre.
2. A letter and patient information sheet (Appendix 4) explaining the study was sent to each patient close to the time when it was possible for the clinician to treat the patients.

3. A letter was sent to the patient's general practitioner and consultant (Appendix 4) with a summary of the trial information informing them that the patient would be invited to take part.
4. The trial research therapist phoned the patient to explain the trial using the information sheet and a check list to exclude those who did not meet the study criteria. If the patient appeared to meet the study criteria they were given an appointment with the trial research therapist who also made an appointment with a clinician directly after assessment or, in the few cases when that was not possible, within a week of assessment. In cases where it was not possible to contact patients by phone a second letter and information sheet was sent to the patient with a stamped addressed envelope asking them to confirm whether or not they would like to take part and offering them an appointment on a specific date. If the patient did not meet the criteria or did not want to take part a reason was recorded where possible.
5. The trial research therapist checked the entry criteria again on the day of the appointment with the patient and checked they had read and understood the information sheet that was posted to them. Patients that did not fit the entry criteria or did not want to take apart were given an appointment with a clinician. An explanation of refusal was recorded by the trial research therapist if the patient gave a reason. The patients who were willing to take part were given a further verbal explanation of the trial by the trial research therapist who followed the procedure explained on the patient information

sheet. Each question on the consent form was checked to ensure that the patient fully understood the procedure.

6. When the trial research therapist was sure that the patient understood the trial procedure consent forms were issued and signed by the patients (Appendix 4).
7. Following informed consent the trial research therapist completed the baseline assessment with the patient (Appendix 6). The trial research therapist then showed the patient how to fill in the outcome questionnaires (Appendix 5) and left them to complete the questionnaires alone answering any queries if necessary. If a partner or friend accompanied the patient they were asked not to assist the patient when completing the questionnaires.
8. The trial research therapist opened a sequentially numbered randomisation envelope and recorded the number of the envelope and the code for intervention (group 1 or group 2) on the assessment form. The trial research therapist was blind to the randomisation code and passed the information to the clinicians. The clinicians were made aware of the randomisation code by a researcher not otherwise involved in the trial who informed the clinicians in each centre. The coding information was stored in a sealed opaque envelope and not opened until the end of the data analysis.
9. The trial research therapist returned the questionnaires to the trial administrator who entered the assessment and questionnaire data into an SPSS data file and recorded the addresses, telephone numbers and date of baseline assessment in an excel file.

INTERVENTION

Patients were randomised to receive either advice to remain active (advice only group) or advice and a routine course of physiotherapy treatment (therapy group). Both groups were given The Back Book⁴⁷ and information from the book was discussed between the physiotherapist and patient. Advice was directed towards promoting self-management and modifying beliefs and behaviour. Physiotherapy treatment was initiated within the week following randomisation.

Advice only group: A single assessment with a physiotherapist who carried out a physical examination and gave general advice to remain active as specified in the back book. The session lasted for up to one hour.

Therapy group: Physiotherapists undertook a physical examination lasting up to one hour. In accordance with typical physiotherapy practice, they chose a treatment strategy based on their findings but agreed to treat according to a standardised protocol reflecting routine NHS practice.⁶² This included any combination of the following: joint mobilisation and manipulation, soft tissue techniques including stretching, spinal mobility and strengthening exercises, heat or cold treatment, and advice. The protocol specified up to five additional treatment sessions of approximately 30 minutes. Physiotherapists recorded the type and number of treatment sessions.

Recording treatment

The physiotherapists recorded the treatment on a patient treatment questionnaire (Appendix 7) when the patient was discharged from the department. The information was held in the centre where the treatment was carried out in case the patient was re-

referred. The information was stored in the department until the end of recruitment and then entered on a SPSS file separate to the main data file to avoid breaking the randomisation code. If the clinician failed to fill in the questionnaire the patient records were checked by the trial research therapist or a member of the study team.

Collecting and recording follow up data

Baseline assessment dates and follow up dates were recorded on an excel file that prompted the trial administrator to send out questionnaires. The assessment forms and questionnaires were sent a few days before the two, six and 12 month follow up dates with a pre-paid addressed envelope. If they were not returned within two weeks they were re-mailed. In the case of non response the trial research therapist then phoned the patients to ask if they would return the questionnaires or be prepared to fill in the primary outcome questionnaire over the phone. If necessary an additional copy of the questionnaires were sent. Data were double entered by the trial administrator who remained blind to treatment allocation throughout data entry.

RANDOMISATION

The allocation sequence was determined prior to the study by a trial administrator using computerised generation of a random number sequence.¹⁹⁵ Groups were coded (1=therapy, 2=advice only) and the allocation transferred to opaque, sealed, sequentially numbered envelopes. No stratification was used as the sample size was large enough to expect equal distribution of patient characteristics in both arms of the trial.¹⁶¹

ALLOCATION CONCEALMENT

The allocation was concealed from the research therapist who carried out the baseline assessment, the data manager who recorded the data, and the statistician carrying out the data analysis. The code for the grouping was known only to the physiotherapists treating the patients. For each participant, the allocation was concealed until the time of the first physiotherapy appointment.

BLINDING

The study was investigator blind but beyond the baseline assessment it was not possible to mask the intervention from the patients or the treating physiotherapists for practical reasons.

SAMPLE SIZE ESTIMATION

In order to calculate the sample size for a trial a primary outcome needs to be selected and the sample size has to be large enough to avoid a type 2 error. In this trial the ODI was chosen as the primary outcome because it had been shown to be a valid and reliable measure of back pain disability.^{168 185} At the time the protocol was developed there was no information recommending a clinically meaningful differences on the Oswestry Disability Index ODI. Data from a study of a similar patient population with a baseline mean ODI of approximately 24% was used.¹⁴⁰

Differences between groups in that study of physical fitness exercise versus backschool were in the order of 3-4% with an approximate standard deviation of mean change scores of 8%. Examples of a 4% difference on the ODI are as follows:

No pain compared with moderate pain; or moderate pain compared with very severe

pain; or able to lift light or medium weights compared with unable to lift anything; or able to sit for up to one hour compared with less than ten minutes.¹⁴⁵

The change in mean response between the groups was taken as 4% at the 0.05 significance level. The 0.05 significance level means there is less than a 5% chance that the results would be due to random error and the null hypothesis could be rejected. The power of the study is the degree of certainty to detect a difference between the groups if one exists. The sample size and power was estimated using the formula in Box 2 described by Pocock.¹⁶¹ We needed 112 patients in each arm of the trial, giving a total sample size of 224 assuming a power of 80% and an alpha of 0.05. We intended to recruit a total of at least 270-300 participants to account for possible drop out at the 12 months. See Table 10 and 11 for further details of power calculations.

Box 2. Formula for power calculation

$$N = 2\sigma^2 / (\mu_2 - \mu_1)^2 \times f(\alpha, \beta)$$

- σ = Standard deviation of mean difference in treatment 1
 $(\mu_2 - \mu_1)$ = Estimated change in mean difference between groups
 f = A function of α and β
 α = The level of the significant test used for detecting a treatment difference. Commonly called type 1 error. The probability of detecting a significant difference when the treatments are really equally effective (i.e. it represents the risk of false –positive)
 β = Commonly called type 2 error, the probability of not detecting a significant difference when there really is a difference (i.e. it represents the risk of false-negative)

$$n = 2(8^2) / (6-2)^2 \times (10.5)$$

$n = 128/16 \times 10.5 = 84$ for 4% difference between groups assuming ***an alpha of 0.05 (2-sided) with 90% power.***

$$n = 2(8^2) / (5-2)^2 \times (7.9)$$

$n = 128/9 \times 7.9 = 112$ for 3% difference between groups assuming ***an alpha of 0.05 (2 sided) with 80% power***

Case difference	control difference	standard deviation	number in group
6	2	8	63
6	2	7	48
5	2	8	112

Table 10. Sample size needed in the each group to detect a given difference at $p<0.05$ (2-sided) with 80% power.

Case difference	control difference	standard deviation	Power
6	2	8	94%
5	2	8	76%
4	2	8	42%
6	2	7	98%
5	2	7	86%
4	2	7	52%

Table 11. Power to detect a given difference including 100 patients in each group

STATISTICAL ANALYSIS

Data screening

Prior to analysis of the trial results the data were checked for errors in the categorical and continuous data. Data were explored to check for data distribution and outliers. Frequencies were checked for categorical data and extreme outliers were double checked by referring back to the original questionnaires. Data distributions were checked to ensure parametric assumptions were met and non-parametric analyses were used where appropriate.

Comparing groups

Independent t-tests (or Mann-Whitney U tests) for continuous data and chi squared tests for categorical data were used for unadjusted comparisons. Analysis of covariance (ANCOVA) was used to assess the effects of treatment at each individual time point with baseline outcome measure scores as the covariate, and adjusting for the between subject factors of age, gender, smoking status and time since first episode of back pain. Effects of treatment over all time points were examined using repeated measures ANCOVA. The differences between the groups in terms of perceived benefit of physiotherapy were assessed using relative risk (RR). The data were analysed using SPSS/PC version 10.0¹⁹⁶

Effect size statistics

The magnitude of the change between 0 and 12 months was expressed as an effect size. The effect sizes can be translated into benchmarks for assessing the relative

size of change between different outcomes. An effect size of 0.2 is considered small, 0.5 medium and 0.8 or greater large.¹⁹⁷ An effect size of 1 is equivalent to a change of one standard deviation in the sample.¹⁹⁸ Effect size statistics are discussed in more detail in chapter eight.

Analysis of covariance (ANCOVA)

ANCOVA compares the variance (variability in scores) between the different groups (believed to be due to the independent variable) with the variability within each group (believed to be due to chance). An F ratio is calculated which represents the variance between the groups, divided by the variance within the groups. A covariate is a continuous variable that may influence scores on the dependent variable.

ANCOVA is a particularly useful test when small sample sizes are used or when small or medium effect sizes are expected.¹⁹⁹

Covariates usually reduce error variance and increase the chance of detecting a significant difference between groups. Covariates need to be reliable, continuous variables that correlate with the dependent variable.¹⁹⁹ Baseline scores were considered as the main confounding factor and used as the covariate in the analysis as there is evidence that severity of symptoms can influence outcome.^{200 201} In addition, gender, age smoking status and recalled duration of back pain have been found to be predictors of back pain and the ANCOVA was adjusted for these factors.^{200 202}

Assumptions of ANCOVA

There are a number of assumptions that apply to ANCOVA that were checked prior to analysis. Whilst these are accepted criteria, ANCOVA is relatively robust particularly when the sample size is reasonably large as in this study. The assumptions include the following:

Level of measurement: The dependent variable is measured at interval or ratio level

Random sampling: Scores are obtained using a random sample.

Independence of observations: The observations or measurements must be independent of one another and violation of this assumption is very serious according to Stevens (1996).²⁰³ Each measurement in this trial was taken from different individuals in isolation so no interaction between observations was possible.

Normal distribution: Scores come from normally distributed samples with the same standard deviation. Violation of this assumption is not serious in studies with a large enough sample size (30+).

Homogeneity of variance: Scores are obtained from populations of equal variance i.e. the variability of scores for each of the groups is similar. To test this the Levene test for equality of variance was checked but ANCOVA is reasonably robust to violation of this assumption.¹⁹⁹

Measurement of covariate: The covariate is measured prior to the intervention.

Reliability of the covariate: The covariate is measured without error.

Correlation amongst the covariates: The covariates are not strongly correlated with one another.

Linearity: There is a linear relationship between the dependent variable and the covariate for both groups.

Homogeneity of regression slopes: the relationship between the covariate and the dependent variable is the same for each group¹⁹⁹

Missing data

To address potential biases attributable to the incomplete follow up three analyses were carried out:

1. An intention to treat analysis restricting results to those with complete data at all time points.
2. An intention to treat analysis including all data at any time point using the last known value carried forward to replace missing values.
3. A per protocol analysis including data from those patient who complied with the treatment protocol.

Outcome data were compared between the groups in terms of change in scores from baseline (therapy group score minus advice only group score). Non-response bias was assessed at each follow-up point to check the differences between the groups in terms of the characteristics of the completers and non-completers. The potential disadvantage of using the last value carried forward method is discussed in chapter 10.

Chapter 6

Trial results

SYNOPSIS

This chapter presents the trial results in four sections. The first section presents the patients characteristics and progress through the trial. The second section describes the type of treatment received in both groups. The third section presents the differences between groups at 2, 6 and 12 months and the final section presents the results of the per protocol analysis.

RECRUITMENT AND PATIENT CHARACTERISTICS

Five hundred and eight patients were assessed for eligibility and 286 (56.3%) were randomised between October 1997 and January 2001. One hundred and forty four were allocated to the therapy group and 142 to the advice group. The number of patients randomised in the seven centres is shown in Table 12.

Recruitment centre	Process of referral to physiotherapy department	Physiotherapy group	Advice group
Nuffield Orthopaedic Centre (Teaching hospital)	Consultant referral only (Latterly triage clinic)	12	11
Churchill Hospital (Teaching hospital)	GP referral	45	39
Radcliffe Infirmary (Teaching hospital)	GP referral	37	37
Wallingford Community Hospital	GP and consultants referral	11	14
Abingdon Community Hospital	GP and consultants referral	13	18
Horton District General Hospital	GP and consultants referral	20	18
Brookside Practice Reading (Primary care)	GP referral only	6	5
Total		144	142

Table 12. Number of patients recruited in the physiotherapy departments within each centre.

Figure 2 shows the patients' progression through the trial along with the response rate at each time point. Baseline characteristics and outcomes are shown in Table 13 and 14. Although the advice only group had a slightly greater proportion of males and smokers, the groups were well balanced with regard to other baseline measures. An important baseline characteristic to note is the low level of back pain disability reported in both groups indicating only mild to moderate disability.

The majority of patients were referred from general practitioners (89%) and the majority (77%) had experienced back pain for more than 12 months even though patients with sub-acute pain were eligible. This may have reflected the normal

referral pattern from the general practitioners or an indication of long waiting lists in the NHS.

	Therapy group N=144	Advice group N=142
Age years, mean (SD)	41.7 (14.9)	40.0 (13.2)
Sex		
Female	83 (57.6%)	67 (47.2%)
Male	61 (42.4%)	75 (52.8%)
Employed	100 (69.9%)	104 (73.8%)
Smoker	40 (28.0%)	49 (34.5%)
Referral		
GP	130 (90.9%)	126 (88.7%)
Consultant	9 (6.3%)	9 (6.3%)
Triage	4 (2.8%)	6 (4.2%)
Sports clinic	0	1 (0.7%)
Location of pain		
Low back pain only	132 (91.7%)	133 (93.7%)
Buttock pain	54 (37.5%)	57 (40.1%)
Thigh pain	44 (30.6%)	48 (33.8%)
Pain radiating beyond the knee	39 (27.1%)	29 (20.4%)
Parasthesia in lower limb (<i>pain was recorded in more than 1 location in some cases</i>)	46 (31.9%)	43 (30.3%)
Length of back pain episode		
6 to <12 weeks	32 (23.0%)	35 (25.5%)
3 to <6 months	35 (25.2%)	31 (22.6%)
6 to <12 months	23 (16.5%)	22 (16.1%)
12 months or more	49 (35.3%)	49 (35.8%)
First episode of back pain		
<1 year	27 (20.0%)	26 (19.8%)
1 year to <6 years	51 (37.8%)	54 (41.2%)
6 years to <11 years	26 (19.3%)	25 (19.1%)
11 years and over	31 (23.0%)	26 (19.8%)
Previous treatment for low back pain	84 (58.3%)	86 (60.6%)

Table 13. Baseline patient characteristics (demographic and health status measures) of all 286 patients included at randomisation. Data are presented as n (%) unless stated otherwise.

Outcomes	Therapy group (n=144) Mean (SD)	Advice group (n=142) Mean (SD)
Roland and Morris Disability questionnaire, mean (SD)	6.12 (4.39)	5.91 (4.27)
Oswestry Disability Index, mean (SD)	21.1 (11.08)	21.60 (11.00)
Patient Specific Activity Questionnaire (main complaint), mean (SD)	4.96 (2.29)	5.22 (2.09)
SF-36 mean (SD)		
Physical functioning	69.3 (19.3)	68.7 (22.8)
Role physical	43.2 (40.6)	44.3 (39.8)
Bodily pain	42.7 (18.1)	44.6 (20.5)
General health	66.6 (19.2)	68.5 (18.9)
Vitality	52.7 (19.2)	53.5 (17.6)
Social functioning	73.6 (25.9)	77.5 (22.4)
Role emotional	72.0 (38.7)	73.5 (38.4)
Mental health	70.0 (16.5)	72.8 (16.0)
Physical Component Summary	49.6 (9.6)	50.4 (10.4)
Mental Component Summary	49.4 (9.7)	50.6 (10.3)

Table 14. Baseline outcome scores of all 286 patients included at randomisation.

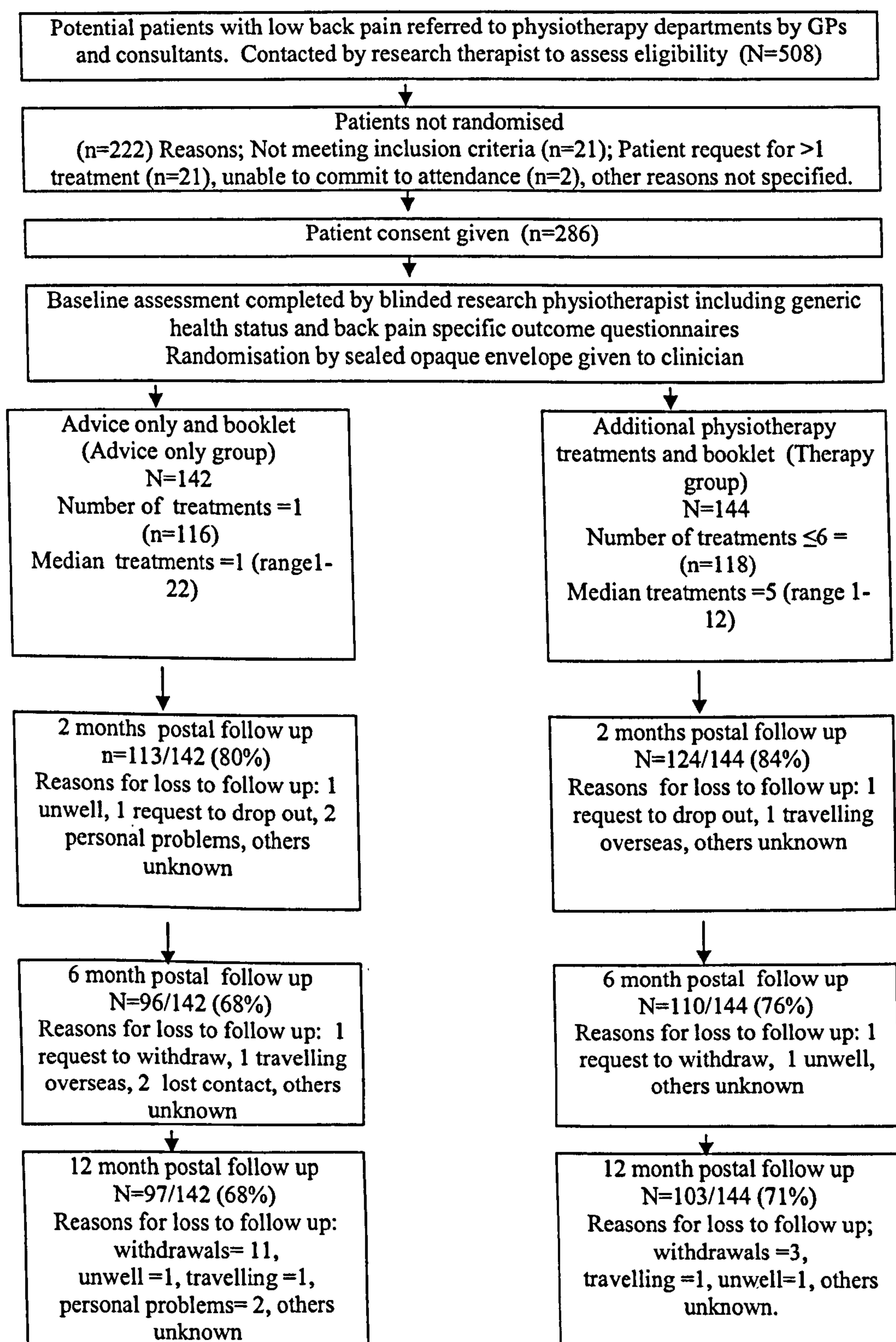


Figure 2. Patients progress through the trial.

(Follow up figures relate to main outcome measures)

TREATMENT

Patients were treated by seventy six physiotherapists reflecting the high turnover of staff in NHS hospitals. About half (53%) of all treatments were carried out by Senior 1 physiotherapists (n=29), 32% by Senior 2 physiotherapists (n=25) and the remainder by junior grades (n=22). Treatment given in the therapy intervention group included low velocity thrust joint mobilisation (n=104, 72%) soft tissue techniques (n=20, 14%), specific exercise (e.g. McKenzie regimes, abdominal stability/strengthening exercises and general lumbar spine mobility exercises) (n=136, 94%), heat (n=9, 6%), and cold treatment (n=4, 3%). The use of high velocity thrust spinal manipulation was rare (n=4, 3%).

The type and frequency of treatment given in the physiotherapy and advice groups are shown in Figure 3 and 4. Some patients were given more than one type of treatment and taught more than one type of exercise. The different types of exercises are shown in Figure 5.

TREATMENT COMPLIANCE

Compliance with the treatment protocol was 82% for both groups. The median number of sessions in the therapy group was 5 (range 1-12) with 118 (82%) being six or fewer. Twenty-six (18%) patients received more than six sessions as a result of clinical decisions made by the physiotherapist. In the advice only group the median number of sessions was 1 (range 1-22). The number of single treatment sessions was 116 with 26 patients receiving extra sessions because either:

1. The patient was unhappy with advice only and requested additional treatment (n=8).
2. The physiotherapist deemed that it was unethical to withhold further treatment e.g. sudden increase in severe pain (n=4).
3. The patient was re-referred by their general practitioner for more treatment (n=2).

No reason was given for extra sessions in the other 12 cases.

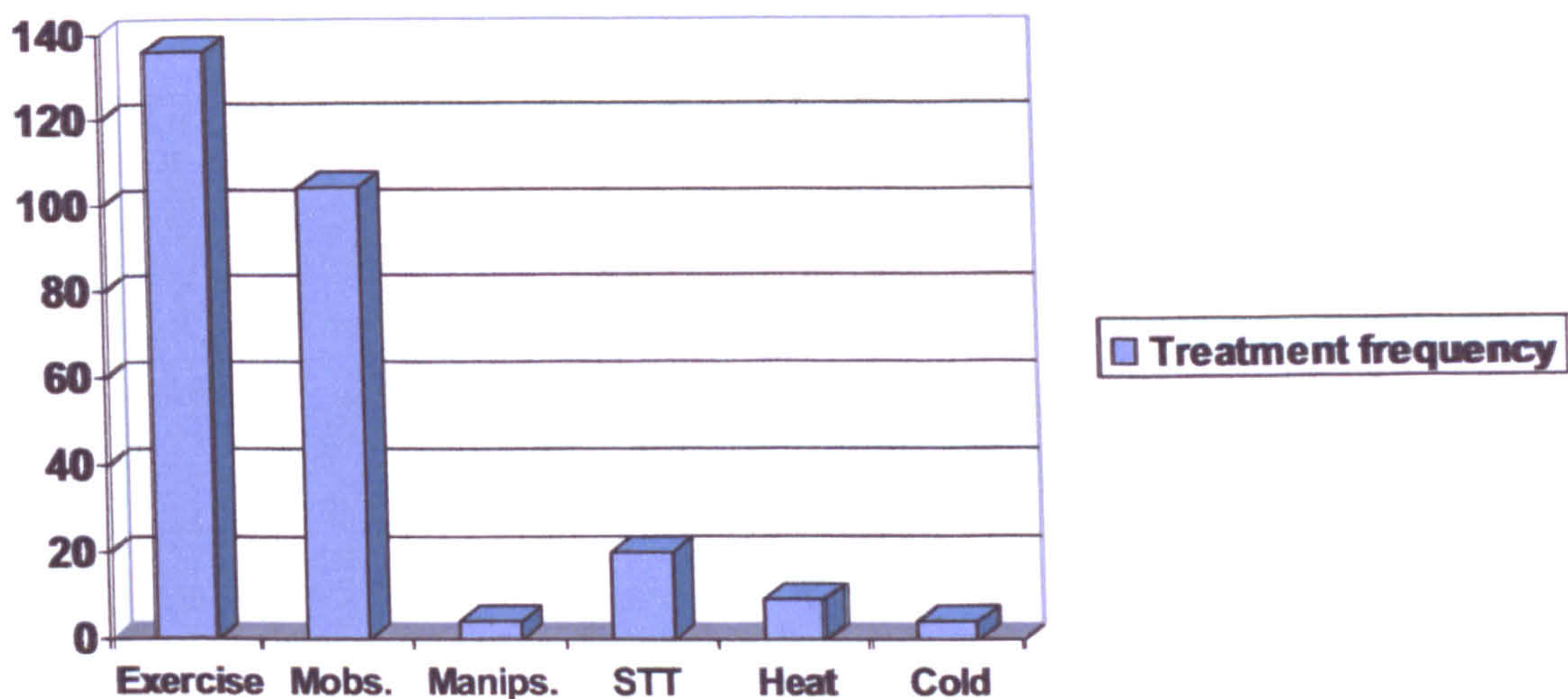


Figure 3. Type and frequency of treatment given in the physiotherapy group

Mobs= joint mobilisation ; Manips = Joint manipulation ; STT= soft tissue techniques ; Heat = hot packs; cold =cryotherapy

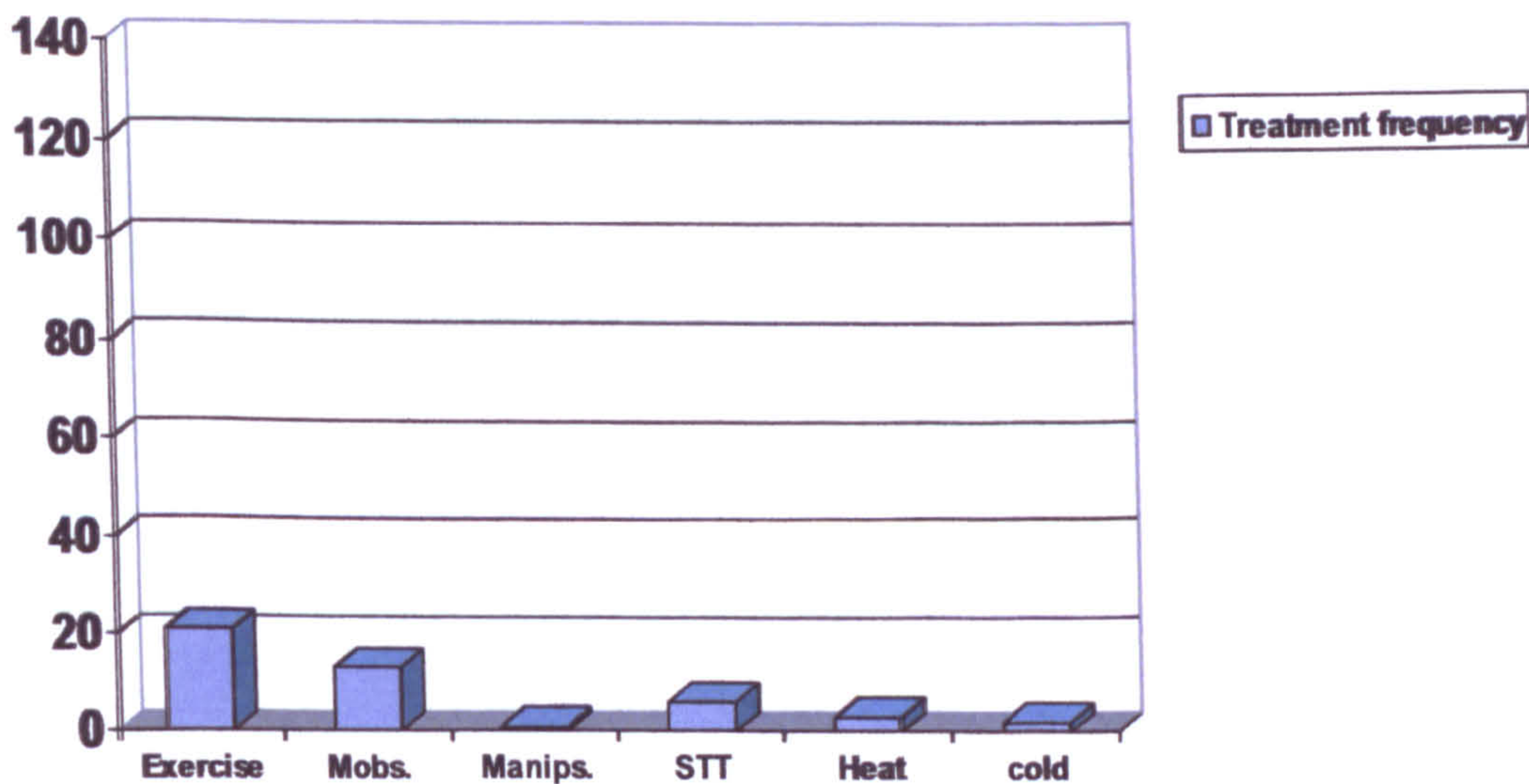


Figure 4. Type and frequency of treatment given in the advice only group in the 18% of patients who did not comply with the protocol

Mobs= joint mobilisation, Manips = Joint manipulation, STT= soft tissue techniques, Heat = hot packs; Cold - cryotherapy

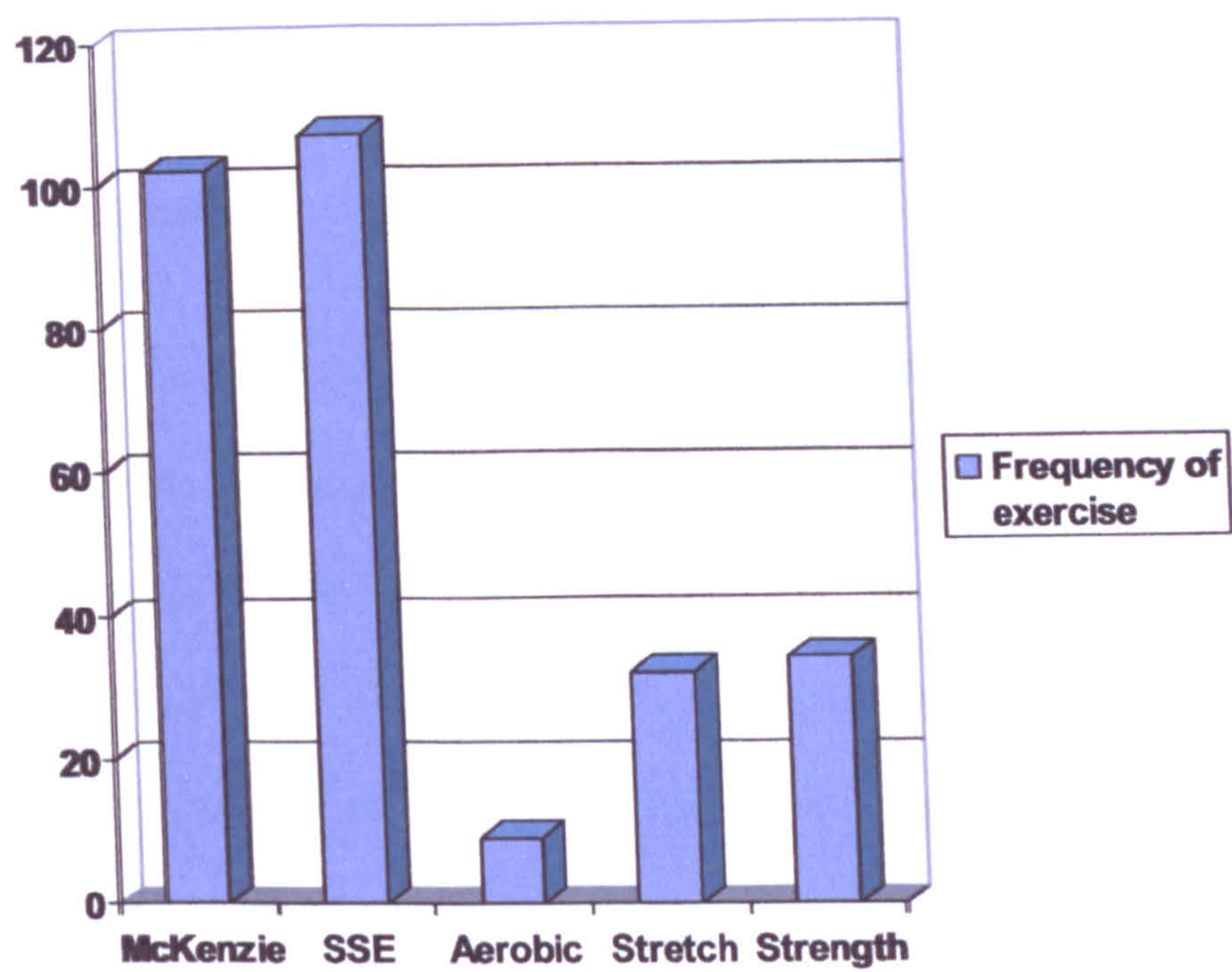


Figure 5. Type and frequency of exercises taught in both groups.

McKenzie= All types of McKenzie exercise

SSE= spine stabilisation exercise

Stretch= spinal stretching and mobilising exercise

Strength= spinal strengthening exercise

NON RESPONSE BIAS

There was a 30% non-response rate at 12 months for the main outcome. However, there were only minor differences in the baseline characteristics of people who completed the Oswestry Disability Index (ODI) at all follow-up points and those who did not. Responders were older {mean age 43 (SD 15) vs 37 (SD 13); $p<0.001$ }, less likely to be a current smoker {39 (22%) vs 50 (47%); $p<0.001$ }, and more likely to be experiencing either their first onset of back pain {39 (23%) vs 14 (15%) $p<0.001$ } or to have a chronic history {43 (25%) vs 14 (15%); $P=.009$ }. There were only small non significant differences between responders and non responders in the advice and physiotherapy group (*Responders*, physiotherapy group mean 20.0 (SD 10.8) and advice group mean 21.3 (SD 10.8); *Non responders*, physiotherapy group mean 22.5 (SD 11.6) advice group mean 22.2 (SD 11.3)) in the primary outcome at baseline.

PRIMARY OUTCOME

No differences were observed in the change in ODI at 12 months between the therapy and advice only group using both last value carried forward and raw data analysis (Mean difference -1.04, 95% CI -3.7 to 1.59). Tabulated results are derived from the last value carried forward method (Table 15).

SECONDARY OUTCOMES

Changes in other health outcomes based on the last value carried forward analysis are shown in Table 16. Mean difference at 12 months in domain scores of the SF-36 were as follows; physical function 2.76, 95% CI -1.91 to 7.42; role physical 0.68, 95% CI -9.54 to 10.9; bodily

pain 6.16, 95% CI 0.45 to 11.9; general health -0.31, 95% CI -4.15 to 3.53; vitality 1.45, 95% CI -2.41 to 5.32; social functioning 3.26, 95% CI -2.39 to 8.91; role emotional 8.65, 95% CI -0.87 to 18.2; mental health 2.19, 95% CI -1.59 to 5.97. Patients in the therapy group reported greater improvement than the advice only group on two domain scores of the SF-36 at two months:- Mean difference 95% CI ; Mental health 4.91 (1.79 to 8.06) ($p<0.006$) and physical functioning 3.55 (-0.52 to 7.61) ($p<0.037$). However, the non-significant repeated measures ANCOVA suggest that these results are likely to be attributable to multiple testing. Multiple significance testing gives a higher probability of finding a significant difference by chance because each test has a 5% chance of a false positive result when there is no real difference (type 1 error).¹⁶⁵

Overall the data are consistent with no benefit from additional physiotherapy. Results based on raw data and last value carried forward analysis produced similar results.

Patient perceived treatment benefit

In contrast with the results of the validated disease specific and generic measures, patients in the therapy group were more likely to report treatment benefit at both 2 and 6 months and also more benefit on the 0-10 rating scale at all time points when compared with the advice only group (Table 17). At the 2 month follow up 93 (76.9%) patients in the physiotherapy group perceived benefits of treatment compared with 64 (59.8%) patients in the advice group. (Table 18) This was statistically significant using a chi-squared test for comparison of categorical data.

PER PROTOCOL ANALYSIS

The results of the per protocol analysis were very similar to the intention to treat analysis. This analysis included 234 (81.8%) patients in total; 118/144 (81.9%) in the physiotherapy group (patients who had 6 or less sessions) and 116/142 (81.7) in the advice group (patients who had one session only). The results for the main outcomes and patient perceived benefits are presented in Table 19 to 21.

Therapy group (n=144)		Advice only group (n=142)		Mean difference (95% CI)		P-value: t-test (ANCOVAa)		Repeated measures ANCOVA p-value a	
	Mean (SD) Change	Effect size	Mean (SD) change	Effect size					
ODI (%)									
2 months	-2.65 (9.34)	0.24	-1.33 (9.29)	0.12	-1.32 (-3.50 to -0.86)	.20 (.17)			
6 months	-2.89 (11.59)	0.26	-1.83 (10.61)	0.17	-1.06 (-3.66 to 1.54)	.36 (.31)			
12 months	-3.27 (10.99)	0.29	-2.23 (11.47)	0.20	-1.04 (-3.70 to 1.59)	.33 (.28)		.24	
RMDQ									
2 months	-1.13 (3.98)	0.26	-0.56 (3.38)	0.13	-0.56 (-1.42 to 0.30)	.20 (.32)			
6 months	-1.19 (4.74)	0.27	-0.79 (4.20)	0.18	-0.40 (-1.44 to 0.64)	.45 (.61)			
12 months	-1.36 (4.66)	0.31	-0.99 (4.23)	0.23	-0.38 (-1.41 to 0.66)	.48 (.62)		.46	
PSAQ									
2 months	1.33(2.64)	0.58	1.23 (2.59)	0.59	0.10 (-0.59 to 0.79)	.77 (.64)			
6 months	1.88 (2.46)	0.72	2.24 (2.97)	0.91	-0.36 (-1.12 to 0.40)	.35 (.72)			
12 months	1.67 (2.71)	0.65	2.22 (2.94)	0.86	-0.55 (-1.36 to 0.25)	.18 (.68)		.56	

a effect of group adjusting for baseline score, age, gender, smoking status, and time since first episode of back pain.

ODI= Oswestry Disability Index

RMDQ =Roland and Morris Disability questionnaire

Table 15. Mean (SD) change in disease specific scores from baseline to 2, 6 and 12 months with missing data replaced using the last value carried forward

Therapy group (N=144)			Advice only group (N=142)		Mean difference (95% CI)		P-value: t-test (ANCOVA)		Repeated measures ANCOVA	
	Mean (SD) Change	Effect size	Mean (SD) change	Effect Size						
Physical function										
2 months	5.24 (19.99)	0.27	1.70 (16.10)	0.07	3.55 (-0.52 to 7.61)	.09 (.037)				
6 months	5.43 (18.80)	0.28	2.77 (17.07)	0.12	2.66 (-1.53 to 6.86)	.21 (.098)				
12 months	5.98 (20.98)	0.31	3.22 (18.87)	0.14	2.76 (-1.91 to 7.42)	.25 (.095)			.06	
Role Physical										
2 months	14.99 (39.35)	0.37	10.80 (35.77)	0.27	4.19 (-4.57 to 12.9)	.35 (.60)				
6 months	15.91 (46.41)	0.39	14.26 (38.87)	0.36	1.65 (-8.31 to 11.6)	.74 (.97)				
12 months	13.89 (45.11)	0.34	13.20 (42.70)	0.33	0.68 (-9.54 to 10.9)	.90 (.83)			.97	
Bodily pain										
2 months	9.70 (20.53)	0.54	7.47 (19.33)	0.37	2.22 (-2.41 to 6.87)	.35 (.39)				
6 months	13.35 (22.88)	0.74	10.49 (21.78)	0.51	2.86 (-2.34 to 8.06)	.28 (.37)				
12 months	16.79 (24.34)	0.93	10.63 (24.70)	0.52	6.16 (0.45 to 11.9)	.035 (.057)			.16	
General health										
2 months	-0.15 (14.23)	0.01	-0.24 (12.76)	0.01	0.09 (-3.05 to 3.24)	.95 (.73)				
6 months	-1.36 (16.01)	0.07	0.06 (13.97)	0.00	-1.42 (-4.92 to 2.08)	.43 (.16)				
12 months	-1.66 (15.92)	0.09	-1.35 (17.05)	0.07	-0.31 (-4.15 to 3.53)	.87 (.62)			.39	

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Vitality									
2 months	2.01 (16.26)	0.11	0.62 (13.74)	0.04	1.39 (-2.11 to 4.90)	.44 (.30)			
6 months	1.77 (17.87)	0.09	1.17 (13.30)	0.07	0.60 (-3.07 to 4.26)	.75 (.72)			
12 months	2.55 (17.85)	0.13	1.09 (15.26)	0.06	1.45 (-2.41 to 5.32)	.46 (.43)			.57
Social function									
2 months	6.25 (22.08)	0.24	1.67 (19.54)	0.07	4.58 (-0.17 to 9.43)	.06 (.24)			
6 months	8.51 (25.16)	0.33	2.64 (20.02)	0.12	5.87 (0.58 to 11.2)	.03 (.12)			
12 months	5.90 (25.13)	0.23	2.64 (23.39)	0.12	3.26 (-2.39 to 8.91)	.26 (.67)			.28
Role emotional									
2 months	6.53 (39.61)	0.17	1.41 (36.57)	0.04	5.12 (-3.77 to 14.0)	.26 (.36)			
6 months	3.03 (36.02)	0.08	-0.94 (41.63)	0.02	3.97 (-5.11 to 13.0)	.39 (.46)			
12 months	5.36 (40.66)	0.14	-3.29 (40.93)	0.09	8.65 (-0.87 to 18.2)	.08 (.065)			.21
Mental health									
2 months	2.46 (13.17)	0.15	-2.45 (13.67)	0.15	4.91 (1.79 to 8.06)	.002 (.006)			
6 months	1.15 (14.46)	0.07	-1.41 (14.88)	0.09	2.55 (-0.86 to 5.97)	.14 (.22)			
12 months	0.64 (15.89)	0.04	-1.55 (16.56)	0.10	2.19 (-1.59 to 5.97)	.26 (.25)			.10

a effect of group adjusting for baseline score, age, gender, smoking status, and time since first episode of back pain

Table 16. Mean (SD) change in SF-36 domain scores from baseline for the two study groups at 2, 6 and 12 months with missing data replaced using the last value carried forward

Patient perceived benefit		Therapy group (n=144)	Advice only group (n=142)	RR of benefit (95% CI)	P-value chi squared
2 months					
Perceived benefit		93 (76.9%)	64 (59.8%)	1.29 (1.07 to 1.54)	.009
No perceived benefit		28 (23.1%)	43 (40.2%)		
6 months					
Perceived benefit		82 (64.6%)	56 (50.5%)	1.28 (1.02 to 1.60)	.039
No perceived benefit		45 (35.4%)	55 (49.5%)		

Table 17. Patient perceived benefits of treatment at 2, 6 and 12 months post randomisation with missing data replaced using the last value carried forward.

Patient perceived benefit? (0-10 scale)		Mean difference (95% CI)		P-value: t-test (ANCOVA a)
2 months	5.42 (2.84) n=119	3.66 (2.78) n=103	1.76 (1.01 to 2.51)	.001 (<.001)
6 months	4.74 (3.24) n=125	3.61 (2.98) n=109	0.93 (0.03 to 1.83)	.006 (.002)
12 months	5.02 (3.12) n=126	4.13 (2.95) n=112	0.87 (0.02 to 1.72)	.025 (.011)

a effect of group adjusting for age, gender, smoking status, and time since first episode of back pain.

Table 18. Patient perceived benefits of treatment at 2, 6 and 12 months post randomisation with missing data replaced using the last value carried forward.

Physiotherapy group		Advice only group	p-value (t-test)	p-value (M-W test)	ANCOVA	
ODI						
0-2 months	-3.34 (9.12)	-1.82 (8.36)	.187	.081	.105	.191*
0-6 months	-3.68 (11.16)	-2.20 (10.0)	.287	.474	.213	
0-12 months	-3.46 (10.64)	-2.81 (10.96)	.644	.391	.487	
RMDQ						
0-2 months	-1.37 (3.90)	-0.74 (3.40)	.188	.336	.433	.630*
0-6 months	-1.52 (4.56)	-1.01 (4.23)	.378	.439	.724	
0-12 months	-1.42 (4.72)	-1.08 (4.15)	.562	.797	.846	

Table 19. Per protocol analysis. Mean (SD) change in disease specific scores from baseline for the two study groups at 2, 6 and 12 months with missing data replaced using the last value carried forward

* repeated measure ANCOVA

Physiotherapy group						Advice only group		p-value (t-test)	p-value (M-W test)	ANCOVA
SF-36										
Physical function										.133*
0-2 months	7.30(18.24)					3.56(15.97)		.098	.086	.034
0-6 months	6.06(19.63)					4.17(17.59)		.441	.471	.238
0-12 months	6.31(22.07)					5.21(19.36)		.685	.498	.381
Role Physical										.847*
0-2 months	17.66(39.92)					13.00(37.50)		.359	.340	.871
0-6 months	18.57(47.82)					16.59(41.04)		.735	.750	.474
0-12 months	15.04(46.82)					16.38(45.10)		.824	.922	.654
Bodily pain										.297*
0-2 months	11.12(21.01)					8.16(20.09)		.273	.626	.399
0-6 months	14.31(23.06)					10.86(21.45)		.237	.343	.289
0-12 months	16.30(25.35)					11.44(25.25)		.144	.162	.424
General health										.411*
0-2 months	-0.38(13.76)					0.15(12.69)		.761	.736	.269
0-6 months	-1.10(16.03)					0.28(14.15)		.488	.331	.601
0-12 months	-1.87(16.22)					-1.00(16.97)		.689	.440	.621

Physiotherapy group		Advice only group	p-value (t-test)	p-value (M-W test)	ANCOVA
Vitality					.650*
0-2 months	1.95(16.64)	1.24(14.10)	.724	.773	.519
0-6 months	2.08(18.33)	1.44(14.34)	.767	.830	.742
0-12 months	2.39(18.39)	2.07(15.67)	.887	.980	.815
Social function					.515*
0-2 months	7.94(21.72)	3.99(19.12)	.141	.253	.209
0-6 months	9.96(24.49)	4.63(19.82)	.069	.239	.763
0-12 months	6.25(24.56)	5.28(23.15)	.756	.855	.406
Role emotional					.386*
0-2 months	8.55(37.69)	4.02(35.48)	.347	.218	.876
0-6 months	3.13(34.74)	2.30(43.01)	.871	.606	.224
0-12 months	5.41(38.15)	0.00(41.93)	.304	.331	.420
Mental health					.212*
0-2 months	2.33(12.88)	-2.17(14.17)	.012	.025	.460
0-6 months	0.90(14.44)	-0.59(15.57)	.450	.557	.769
0-12 months	0.56(16.24)	0.07(16.07)	.817	.948	.014

Table 20. Per protocol analysis. Mean (SD) change in SF-36 domain scores from baseline for the two study groups at 2, 6 and 12 months with missing data replaced using the last value carried forward

* repeated measure ANCOVA

	Physiotherapy group	Advice only group	p-value (t-test)	p-value (M-W test)	ANCOVA
How much benefit					<.001*
2 months	5.61(2.72)	3.44(2.71)	<.001	<.001	<.001
6 months	4.96(3.12)	3.45(2.86)	.001	.001	<.001
12 months	5.09(3.05)	4.00(2.72)	.009	.008	.004

Table 21. Per protocol analysis. Mean (SD) benefit measured on a 0-10 scale (10 = maximum benefit) at 2, 6 and 12 months

* repeated measure ANCOVA

SUMMARY OF RESULTS

The trial took three years to recruit 286 patients between 1997 and 2001. This was longer than anticipated and reasons for this are discussed in chapter ten. The baseline level of disability in both groups was lower than most other trials of therapy for sub-acute and chronic low back pain suggesting minimal/moderate disability. The majority of patients (77%) had back pain for more than 12 months and 89% of patients were referred from general practitioners. Sixty percent of patients had received previous treatment for back pain.

Trial follow up rates were 80%, 68% and 68% in the advice group and 84%, 76% and 71% in the physiotherapy group at 2, 6 and 12 months. Imputation of data was carried out using the last value carried forward method.

Treatment compliance was 82% in both groups and the additional treatments received in the advice group ranged from 1 to 22. The most common treatments given in the physiotherapy group were exercise and low velocity joint mobilisation which was a true reflection of routine treatment given in the NHS.

No evidence was found that routine physiotherapy treatment was more effective than a single session of assessment and advice given by a physiotherapist for the primary or secondary outcome measures, therefore the null hypothesis was accepted. Both groups improved over time in most outcomes but the effect sizes were generally low (<0.5) particularly for the primary outcome.

In the short term 2 month follow up there were trends in favour of the physiotherapy group with a statistically significant difference between groups in the mental health dimension of the SF-36 at 2 months (mean difference (95% confidence interval) 4.91 (1.79 to 8.06); $p < 0.002$) and bodily pain score at 12 months (mean difference (95% confidence interval) 6.16 (0.45 to 11.9); $p < 0.04$). These were unlikely to be clinically significant.

Statistically significant higher patient perceived benefits were reported between groups in favour of the physiotherapy group at 2, 6 and 12 months.

Chapter 7

Trial treatment costs

SYNOPSIS

This chapter reports the financial cost of the trial treatment. The data collection methods and analysis of NHS and private costs are described with an aim to compare overall cost of the two treatment strategies.

METHODS

Postal assessment questionnaires were sent to patients at each follow-up point (two months, six months and 12 months) to gather resource use data (Appendix 6)

Patients were given diaries at the baseline assessment to help them complete the follow up questionnaires accurately (Appendix 6). The data collected at each stage of the trial are shown in Figure 6

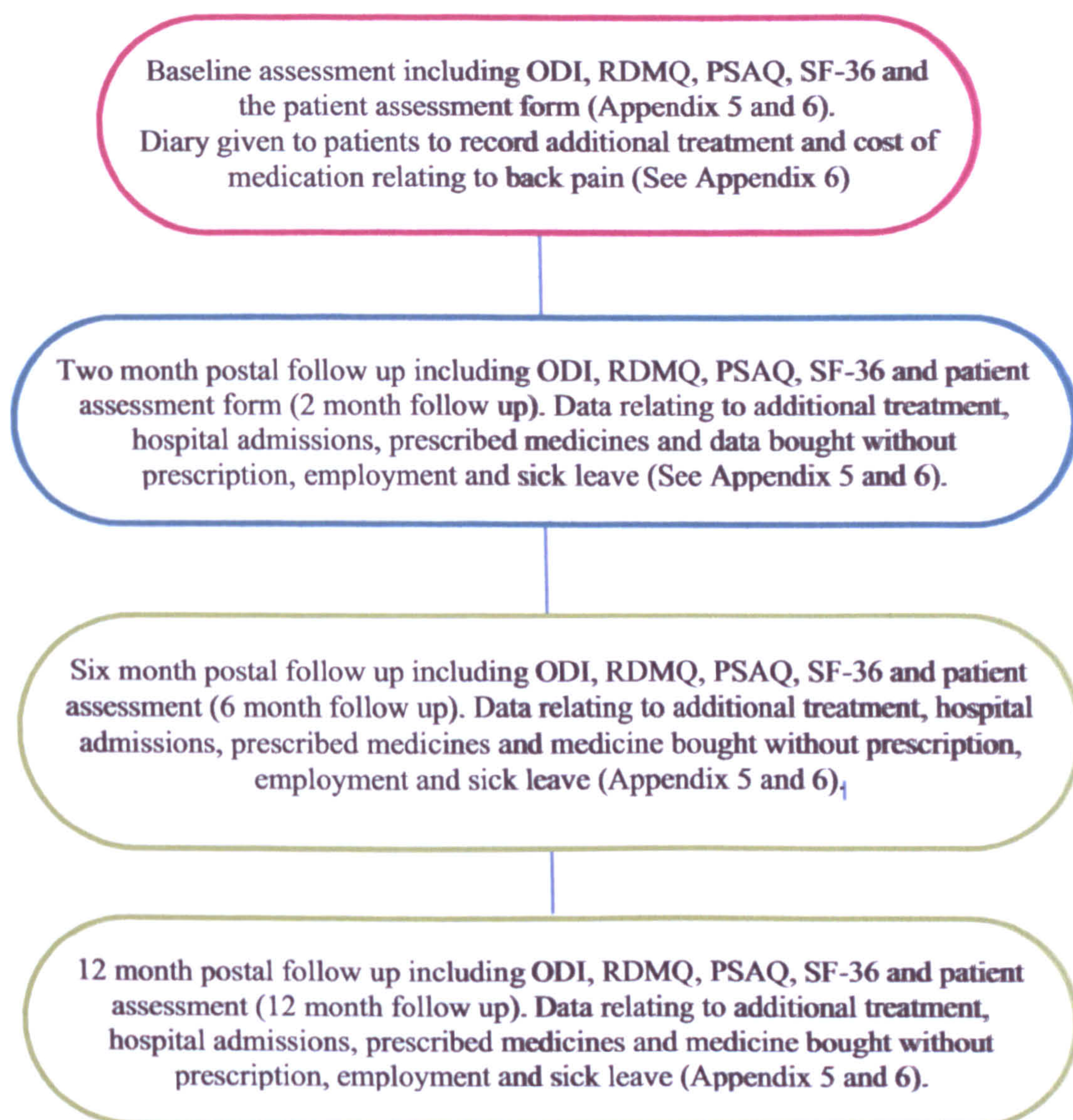


Figure 6. Resource use and cost data collected at each stage of the trial

Three main resource use categories were included in the analysis which adopted both a National Health Service (NHS) and societal perspective. NHS costs included the costs associated with the interventions and other back pain related NHS services used by the patients during the length of the trial, including general practitioner visits, NHS consultant visits, NHS physiotherapists' visits, hospitalisation and prescribed items. Health care purchased directly by the patients included private consultations with osteopaths, chiropractors and other practitioners, and the costs of medicines purchased by the patients. Employment costs included the number of days off work experienced by the patient due to back pain symptoms.

Unit cost sources

Unit costs were obtained mainly from standard publications.²⁰⁴ The daily cost in hospital was calculated using the specialty specific cost per inpatient day based on the average of financial returns from up to 241 hospitals across England.²⁰⁵ Private practitioners' unit costs were obtained from the relevant national organisations. The cost of the "Back Book" used in the intervention was obtained from The Stationery Office.⁴⁷ The cost per days off work was obtained from the New Earning Survey.²⁰⁶

NHS costs

For each patient, the volume of NHS and other health care resources used was recorded and multiplied by its unit cost yielding the total health care cost per patient and the mean cost in each arm of the study. The cost of days off work (employment costs) was calculated in the same way, but is reported separately.

Statistical analysis

The mean (standard deviation) cost per patient was computed for the physiotherapy and advice groups respectively. The mean difference between groups and the associated 95% confidence interval were calculated using parametric techniques. The null hypothesis of no mean difference in cost was tested using the independent t-test. Skewness of data was assessed before parametric methods were employed.

Completeness of the data

Forty nine percent of patients in the study had at least one item of resource use information missing, and in total 24% of all resource use data items were missing. There was no evidence of differences in baseline characteristics between responders (patients who filled all the assessment questionnaires in at all the follow-up periods) and non-responders (patients who did not fill the assessment questionnaires in any of the follow-up periods), suggesting that it was likely that the missing data were missing at random.²⁰⁷ Multiple imputation was used to complete the dataset and 95% confidence intervals were calculated using standard parametric techniques.²⁰⁷ In the analysis, results are reported for all patients with missing data imputed; comparable results for complete cases only are reported in the sensitivity analysis.

Sensitivity analysis

Uncertainty was handled mainly through reporting confidence intervals for the difference in costs and effects of the variables of interest. Complete case analysis was undertaken to validate the results derived from the imputed datasets. As the number of patients in the advice group who had physiotherapy sessions (additional

to the one offered in the trial) turned out to be an important cost driver in that group, sensitivity analysis was performed to estimate the impact of this variable on the results.

RESULTS

Resource use and costs

Table 22 shows the mean volume of resources used for each category and the mean difference between study arms. Physiotherapy sessions were divided into those specified by the original protocol and additional sessions. The advice group had more additional sessions than the physiotherapy group and used more other NHS services during the study period, but neither of these differences was significant. Contrary to expectations, the physiotherapy group consumed significantly more private practitioner services than the advice group (mean resource use difference in visits to private practitioner 1.04 (95% CI 0.26 to 1.82). There were no differences in the number of days off work between the two groups.

Table 23 shows a summary of the mean cost per patient for each resource use category and the mean difference between study arms. The physiotherapy intervention cost was on average £52 (95% CI £41 to £63) more expensive per patient than the advice only. Other NHS costs were higher in the advice arm over the study period, but these differences were not significant. The total cost for health care purchased directly by the patients was significantly higher in the physiotherapy arm, a difference of £41 (95% CI £9 to £71). Combining NHS costs and health care purchased directly by the patient, the total health care cost was £264 per patient in

the physiotherapy group and £204.05 in the advice group, a non significant difference of £60 (95% CI -£5 to £126).

Using average earnings by gender, the total employment related costs were £724 in the physiotherapy group and £913 in the advice group, a non significant difference of -£189 (95% CI -£901 to £523).

Sensitivity analysis

The complete case analysis produced the same overall cost results as the multiple imputation analysis. Assuming that the advice group did not receive any additional physiotherapy sessions as specified in the protocol (per protocol analysis) and holding all other variables constant, physiotherapy was significantly more expensive with a mean difference of £78 (CI £13 to £143).

SUMMARY

There were no significant differences between the total NHS cost of physiotherapy intervention and advice given by a physiotherapist for patients with mild to moderate low back pain. This was due to the larger number of additional treatments received in the advice group by a small number of patients who did not follow the protocol (18% of patients in the advice group received more than one session). There were significantly higher out of pocket expenses incurred by patients receiving routine physiotherapy.

Resource units	Physiotherapy Group Mean (SD) n=144	Advice Group Mean (SD) n=142	Mean Difference (parametric 95% CI)
National Health Service costs			
Intervention (physiotherapy sessions)			
A protocol	4.36 (1.68)	1.00 (0)	--
B Additional treatment	0.43 (1.19)	0.90 (2.80)	-0.47 (-0.97 to 0.02)
No of physiotherapy sessions (A+B)	4.79 (2.37)	1.90 (2.80)	2.89 (2.29 to 3.49)*
No of advice booklets	1.00 (0)	1.00 (0)	--
Other NHS Treatments			
No of visits to general practitioner	0.68 (1.31)	0.87 (1.98)	-0.19 (-0.57 to 0.20)
No of visits to NHS consultants	0.14 (0.40)	0.26 (0.73)	-0.12 (-0.26 to 0.02)
No of visits to NHS physiotherapist	0.64 (2.43)	0.91 (2.73)	-0.28 (-0.87 to 0.32)
No of inpatient days	0.16 (1.02)	0.17 (1.10)	-0.01 (-0.25 to 0.24)
No of prescribed items	0.79 (1.68)	1.09 (2.66)	-0.30 (-0.81 to 0.22)
Patient Health Care Costs			
No of visits to private practitioner	2.06 (4.33)	1.02 (2.05)	1.04 (0.26 to 1.82)*
No of over the counter medications for LBP	1.44 (3.44)	1.61 (3.61)	-0.17 (-0.98 to 0.65)
Employment related costs			
Total no days off work	9.48 (34.11)	10.85 (37.68)	-1.37 (-9.60 to 6.85)
* p<0.05			

Table 22. Summary of resource use associated with back pain in the two study groups at 12 months follow up after multiple imputation of missing values.

Resource units	Physiotherapy Group Mean (SD) n=144	Advice Group Mean (SD) n=142	Mean Difference (parametric 95% CI)
National Health Service costs			
Initial treatment costs	£88 (£43)	£36 (£50)	£52 (£41 to £63)*
Other NHS related costs	£91 (£214)	£123 (£249)	-£32 (-£86 to £22)
Total NHS cost per patient	£179 (£221)	£159 (£260)	-£20 (-£36 to £76)
Patient health care costs	£86 (£170)	£45 (£80)	£41 (£9 to £71)*
Total cost per patient (employment-related costs non included)	£264 (£287)	£204 (£277)	£60 (-£5 to £126)
Total employment-related costs included	£724 (£2,810)	£913 (£3,384)	-£189 (-£901 to £523)
*p<0.05			

Table 23. Summary of costs associated with back pain in the two study groups at 12 months follow up after multiple imputation of missing values.

Chapter 8

Responsiveness of the trial outcome measures

SYNOPSIS

Discordance between the results of the patient perceived benefit scores and the other outcomes raised the question of which measures were most responsive in the context of the trial. Responsiveness has previously been assessed in populations of patients with more severe back pain but not for patients who report mild/moderate disability. This chapter reports the responsiveness of the trial outcome measures using effect size and area under the receiver operating characteristics (ROC) curve statistics.

BACKGROUND

There are a wide variety of measures available to assess the outcome of interventions for back pain. They fall into three main categories;

- 1) Generic instruments are able to measure a range of different conditions and diseases to provide a summary of overall health. The usefulness of generic measures lies in their ability to allow comparisons among patients with different as well as the same condition. In addition generic instruments can capture the broader effects of intervention.^{208 209}
- 2) Specific instruments that focus on a particular disease. The narrow focus of specific instruments has the potential to make them more responsive to clinically important change than generic measures.^{209 210}
- 3) Patient specific instruments that allow an individual's perspective to be included in the evaluative process by assessing activities or aspects of health that are deemed to be of particular importance to the patient. The patient specific approach has been

used to assess back pain¹⁷⁰ and other areas of health such as hip replacement,²¹¹ general health²¹² and ankylosing spondylitis.¹⁹⁴

The following criteria are important in the selection of outcome measures for a trial; appropriateness, reproducibility, validity, responsiveness, precision, interpretability, acceptability, feasibility and floor and ceiling effects.²⁰⁸ The terms are defined in Table 24. A systematic review of outcome measures designed to assess functional status or disability for patients with back pain identified 36 back pain specific questionnaires between 1996 to 2002.¹⁸⁰ In order to standardise the use of outcome measures, thereby enabling comparison between trials, a core set of recommendations for back pain research were published in 1998.¹⁷¹ These are summarised in Table 25.

Term	Definition (Fitzpatrick et al 1998, Terwee et al 2007) ^{213 214}
Appropriateness	The extent to which the instrument is appropriate to the question asked.
Reproducibility <i>Agreement</i>	The extent to which the scores on repeated measures are close to each other.
<i>Reliability</i>	The extent to which patients can be distinguished from each other, despite measurement error.
Validity	The extent to which the instrument measures what it purports to measure.
<i>Criterion</i>	Criterion validity relates to a new measure correlating with another measure that is already accepted as a more accurate variable. (It is rare to have a perfect gold standard for this aspect of validity in the back pain field).
<i>Face validity</i>	The terms are related but distinguished in the following way; Face validity refers to what an item appears to measure based on its manifest content.
<i>Content validity</i>	Content validity refers to how well a measurement battery covers important parts of the health component to be measured.
<i>Construct validity</i>	Construct validity is examined by quantitatively examining relationships of a construct to a set of other variables. No single observation can prove the construct of a new measure.
Responsiveness	The ability of the instrument to detect changes over time within individuals that reflect therapeutic effects.
Precision	Precision relates to how precise the scores of the instrument are either numerically or categorically in capturing the full underlying range of problems experienced by the patient
Interpretability	The extent to which the scores of the instrument are interpretable.
Acceptability	The extent to which the instrument is acceptable to the patient.
Feasibility	The extent to which the instrument is easy to administer, process and evaluate.
Floor and ceiling effects	The potential for respondents to achieve the lowest or highest possible score.

Table 24. Criteria for selecting outcome measures for trials.

Term	Definition (Fitzpatrick et al 1998, Terwee et al 2007) ^{213 214}
Appropriateness	The extent to which the instrument is appropriate to the question asked.
Reproducibility <i>Agreement</i>	The extent to which the scores on repeated measures are close to each other.
<i>Reliability</i>	The extent to which patients can be distinguished from each other, despite measurement error.
Validity	The extent to which the instrument measures what it purports to measure.
<i>Criterion</i>	Criterion validity relates to a new measure correlating with another measure that is already accepted as a more accurate variable. (It is rare to have a perfect gold standard for this aspect of validity in the back pain field).
	The terms are related but distinguished in the following way;
<i>Face validity</i>	Face validity refers to what an item appears to measure based on its manifest content.
<i>Content validity</i>	Content validity refers to how well a measurement battery covers important parts of the health component to be measured.
<i>Construct validity</i>	Construct validity is examined by quantitatively examining relationships of a construct to a set of other variables. No single observation can prove the construct of a new measure.
Responsiveness	The ability of the instrument to detect changes over time within individuals that reflect therapeutic effects.
Precision	Precision relates to how precise the scores of the instrument are either numerically or categorically in capturing the full underlying range of problems experienced by the patient
Interpretability	The extent to which the scores of the instrument are interpretable.
Acceptability	The extent to which the instrument is acceptable to the patient.
Feasibility	The extent to which the instrument is easy to administer, process and evaluate.
Floor and ceiling effects	The potential for respondents to achieve the lowest or highest possible score.

Table 24. Criteria for selecting outcome measures for trials.

Domain	Instrument	Response options	Score (best to worse)	Time to complete	Dimensions
Back Specific function ^{178 182}	RDMQ (original)	0-24	0-24	5 minutes	Physical activity, housework, mobility, dressing, getting help, appetite, irritability, pain
	ODI-version 2	10 (6 levels)	0-100	5 minutes	Pain intensity and pain relating to personal care, lifting, sitting, standing, sleeping, sex life (optional), social life, traveling
Generic health status ¹⁶⁷	SF-36 version 2	36 (vary)	8 dimensions; 100-0 each or norm based: Mean 50; SD 10	10 minutes	Physical function, role physical, bodily pain, general health, vitality, social function, role emotional and mental health. Two aggregate component scores: physical and mental health
Pain ¹⁶⁷	Bodily pain scale of SF-36 (chronic pain grade)	2 (vary)	100-0	2 minutes	Pain intensity, pain interference with work and housework
		7 (11pt numerical scale)		5 minutes	Current worse, and average pain, disability days, interference usual activities, recreational social and family activities and work (incl. housework)
Work disability ¹⁷⁷	Work status	10 categories	Nominal scale	1 minute	Employed at usual job, on light duty, or some restricted work assignment, paid leave/sick leave, unpaid leave, unemployed because of health problems, unemployed because of other health problems, unemployed because of other reason, student, keeping house, retired, on disability
	Days off work and days of cut down work	Number of days		2 minutes	
Satisfaction: back specific ¹⁷⁷	Patient satisfaction	17 (5 levels)			Information, caring, effectiveness of treatment, and others
	Global satisfaction	1 (7 levels)	1-7	1 minute	Extremely, very, somewhat satisfied, mixed, somewhat very, extremely dissatisfied

Table 25. Proposed set of outcome measures for use in assessment of spinal disorders

Outcomes used in the trial

The outcome measures chosen for the trial are described in full in the methods chapter. The Oswestry Disability Index version 2 (ODI) and the original Roland and Morris Disability Questionnaire (RMDQ) are the most commonly used back pain specific measures. This is partly due to the recommendations made in 1998¹⁷¹ but also because they have been tested extensively for reliability, validity and responsiveness in various back pain populations.^{178 180 182} Patient specific measures were not recommended by Deyo et al. (1998)¹⁷¹ although they have been reported as reliable, valid and responsive for patients with moderately disabling back pain.¹⁷⁰ They have not been evaluated widely in the back pain field but have the potential to detect changes in specific activities of daily living affected by back pain that are chosen by and therefore relevant to patients.

Similarly the SF-36 has become the established tool of choice for assessing health status due to its sound psychometric properties.^{177 181} However, due to variation in patient populations, an instrument can be valid and responsive in one setting but invalid in another.

Rational for investigation of responsiveness of trial outcomes

There were no differences between groups in any of the main outcomes in the trial but results derived from the patient perceived benefit scale differed from the disease specific and generic measures. This discordance raised the question of whether the main outcomes were responsive in detecting change. In this study the baseline scores were low as all patients, regardless of baseline disability level, were included in the trial. Previous research in this field has focused on populations of back pain

patients with higher disability levels^{181 209 213-219} and therefore this study is a new contribution to the literature.

Definition of responsiveness

There are many definitions of responsiveness but most authors agree that responsiveness involves the ability of a measure to detect change.²²⁰⁻²²³

Beaton (2000)²²⁰ describes four categories of change;

1. Change that can be considered greater than noise (normal variation) alone (minimally detectable change)
2. Change that is observed before and after treatment (observed change)
3. Change in those that have improved according to an external criterion (estimated change)
4. Change in those that have made a major improvement according to an external criterion that is an indication of important change (minimally important change)

Beaton et al. (2001) suggest that many parts of the conceptual debate could be resolved by allowing the different methods of measuring responsiveness to stand as distinct types each depending on the nature of the change described within the study.^{184 221} The authors propose a taxonomy for responsiveness that describes three main features (See Table 25). This study focuses on patient estimated change at the group level.

The Who axis	Who are the results presented for?	Individual level Group level
The Which axis	Which scores are being contrasted?	Between person differences at one point Within person change over time Both 1 & 2: between person differences of within person change
The What axis	What type of change is being quantified	Minimum potentially detectable change by the instruments Minimum change detectable given the measurement error of the instrument Observed change in a population Observed change in a population deemed to have improved by patient, clinician, payer, society (estimated) Observed change in those deemed to have had an important improvement

Table 26. Taxonomy of responsiveness proposed by Beaton et al (2001)

Responsiveness to change in back pain outcomes

Various statistical methods have been used to assess responsiveness.^{180 209 210 216 224-}

²²⁶ The majority of studies focus on the ability of instruments to detect ‘estimated change’ using an external marker of change. Analysis of instrument score changes within each group then provides information on how much change one might expect to see amongst groups of similar patients who improve, deteriorate or for whom there is no change in health status. There is no agreement about a true gold standard for change and there are methodological problems with this approach that are discussed later in this chapter.²²⁷

Floor and ceiling effects

The form of items within a questionnaire may reduce the likelihood of further improvement or deterioration being recorded beyond a certain level. The terms ceiling and floor effects are used to describe this problem.²¹³ Some authors have raised concerns about possible floor and ceiling effects of the SF-36.^{181 189 215} Floor and ceiling effects can be considered in the context of responsiveness but also in relation to precision and distribution of items in questionnaires.²⁰⁸ Most studies evaluating responsiveness in this field have included patients with moderate back pain.^{181 185 215} If patients score in the middle of an instrument's scale at baseline, floor or ceiling effects are less likely to be identified. However, when patients score at the extreme of the instrument's range, floor or ceiling effects are more likely to occur thereby affecting the responsiveness of the measure.

METHODS

Objective

To assess responsiveness of the disease specific, patient specific and generic outcome measures in a population of patients with low back pain of mild to moderate severity.

Outcomes investigated

The trial outcome data measured at baseline and 12 months were analysed. These included the Oswestry Disability Index (ODI),¹⁷⁸ Roland and Morris Disability Questionnaire (RMDQ)¹⁸², eight domains of the short form general health measure (SF-36)^{167 228} and the patient specific activity questionnaire (PSAQ).¹⁷⁰

Global transition rating scale

A global transition rating scale of the patients perceived back pain state was used as the external marker. This information was collected on the 12 month follow up questionnaire. The question was phrased as follows: Is your back pain better, just the same or worse after the physiotherapy advice/treatment you received 12 months ago. The relationship between the global transition rating scale and change in the back pain specific questionnaires (ODI and RMDQ) was investigated to check criterion validity.²²⁹

Data analysis

Statistical analyses were performed using SPSS version 12 (SPSS inc. Chicago, IL).

The distribution of the data were checked by examining normality plots.¹⁹⁹

Descriptive statistics were calculated at baseline and at 12 months for those who completed the 12 month questionnaire in the trial. The data set includes only those patients who responded to the 12 month follow up questionnaire (n=201).

Subjects were divided into three groups defined by the transition rating scale (better, same or worse). The change scores were calculated by subtracting the baseline scores from the follow up scores. Thus a negative change indicated an improvement for the ODI and RMDQ and a positive score indicated an improvement for the patient specific activity questionnaire and the SF-36 dimension scale.

The strength of the relationship between the change in ODI scores (0 to 12 months) and the global transition rating scale was tested using Spearman's Rank Order Correlation.¹⁹⁹

Statistical significant differences between groups (better, same and worse) in baseline and change scores were checked using one way analysis of variance (ANOVA).

Post-hoc tests (Tukey HSD test) were carried out with a Bonferroni correction for multiple testing to assess statistical differences between groups in baseline and change scores.^{165 199}

Assumptions for ANOVA were checked. The Levene's test for homogeneity of variances demonstrated that variance in scores differed between groups. Therefore a more conservative alpha value of 0.01 was set for determining significance testing to reduce the risk of a type 1 error.¹⁹⁹

Effect size statistics were calculated using three different methods.^{197 198 222 230 231}

Area under the receiver operator characteristic curve statistics were calculated to determine responsiveness at the individual patient level.²³² A detailed description of each method is provided below.

Effect size statistics

Effect size statistics measure the ability of a scale to detect a signal (improvement) among the noise (normal variation) of a patient population.^{185 198} There is controversy regarding the best method to calculate effect size.¹⁸⁵ Kazis et al (1989)¹⁹⁷ calculated the difference between the mean scores of a group of patients at baseline and follow-up divided by the standard deviation of the group's baseline scores. This transforms the score change into a standard unit of measurement, which could then be compared with score changes of other instruments, which may be in different units. This ratio was intended to capture the degree to which a scale changes in value above and beyond the standard fluctuation of the baseline scores. Cohen et al (1977)¹⁹⁸ recommends the standardised response mean (SRM) and Guyatt et al (1989)²³⁰ the modified standardised response mean (MSRM). Both use the same numerator as the method used by Kazis et al (1989), but different denominators. For the SRM, the standard deviation of the change in scores between the two assessment points is used. Beurskens et al (1996)¹⁸⁵ argued that the measure of change is a function of the standard deviation of the change scores. The MSRM calculates the standard deviation of change scores for patients who report no change in their symptoms. This accounts for the intrinsic variability of changes in an instrument.²³⁰ For comparison with other studies all three methods were calculated.

An effect size of 1 is equivalent to a change of one standard deviation in the sample. The effect sizes can be translated into benchmarks for assessing the relative size of change, an effect size of 0.2 being considered small, 0.5 as medium and 0.8 or greater as large.¹⁹⁸ Data for the three groups of patients, those that reported improvement, remained the same and deterioration, were analysed.

Receiver-operating characteristic curves (ROC)

Deyo and Centor (1986)²³² reported that an outcome measures ability to distinguish between changing and stable patients could be evaluated in the same way as a diagnostic test using sensitivity and specificity statistics. To determine the sensitivity and specificity of an instrument it is necessary to have information on each patient's true health/back status i.e. whether they are really changed (improved or deteriorated) or stable. Most researchers have used a global measure of patient perceived change or in some cases a combined consensus derived from the patient and clinician.^{179 185 209 233 234} For this analysis patients were coded as improved (those patients who categorised themselves as better) or not improved (those patients who categorised themselves as the same).

An instrument which can discriminate well between patients that improve and those that do not would have a plot where sensitivity sharply increases whilst 1-specificity remains low. The greater the total area under a ROC curve, the greater the instrument's responsiveness.²³² An area of 0.5 indicates no accuracy in detecting change (i.e. at each cut off point true and false positive rates are equivalent). An area of 1.0 indicates perfect accuracy. Confidence intervals for the different areas quantify the uncertainty around the point estimates.

Since the aim of any instrument is to maximise true positive detection whilst simultaneously minimising false positive detection, the ROC curve can be used to identify the change score or cut-off value for an instrument, which simultaneously gives the high values of sensitivity and specificity. Using this 'optimal' cut off value as the threshold for change, one has the highest probability of correctly classifying patients as improved or not. However, there is evidence to suggest that the optimal cut off level will differ depending on the baseline scores of the sample population.^{226 232 235 236}

RESULTS

The sample included 90 male and 111 female subjects with a mean age of 42.5 years (SD 14.4) who completed the 12 month follow up questionnaire. One hundred and nine (54.3%) patients reported their back pain as better, seventy-six (37.7%) reported their back pain as unchanged and 16 (8%) reported deterioration in their back pain.

Figures 6 and 7 show the distribution of change scores for the ODI and RMDQ in patients who reported their back pain as better at 12 months. The box plot (Figure 8) shows the distribution of ODI change scores for each group. The correlation between the transition rating scale and the ODI was 0.47 $p < 0.001$.

Tables 26 and 27 show baseline and 12-month data for the ODI, RDMQ, patient specific activity questionnaire (PSAQ) and SF-36 domain scores for each category (i.e. better, same, worse). For the improved group, baseline scores indicated that the patients were less disabled, in less pain and had better general health than those who reported no improvement or deterioration at 12 months. The differences in baseline scores were significant between the improved and deteriorated group for the ODI ($p < 0.003$ mean differences -9.3 95% confidence interval -15.9 to -2.6) and the improved and stable group for physical function score of the SF-36 ($p < 0.007$ mean difference 9.6 95% confidence interval 2.1 to 17.1). There were statistically significant differences at the $p < 0.01$ level in change score between groups for most outcomes. There were non significant differences for seven domains of the SF-36 and the PSAQ between the same and worse groups. Results of the ANOVA tests

between the change scores for each group (better, same, worse) are shown in Table 27 and 28.

The primary outcome (ODI) demonstrated moderate change scores in the improved (mean -8.32, SD 9.66) and deteriorated group (mean 9.71, SD 15.77) and little change in mean scores in the group who reported no change (mean -0.08, SD 11.6).

In the group of patients who reported deterioration, directional change on all instruments was in line with expectation. The bodily pain item of the SF-36 demonstrated large change scores for the improved group (29.6, SD 19.8) but only a small change in the deteriorated group (mean -5.37, SD 13.2). There was a similar trend for the patient specific activity questionnaire where a large change was seen for the improved group but not for the deteriorated group (improved group 3.0 SD 2.77; deteriorated group -0.37, SD 2.22).

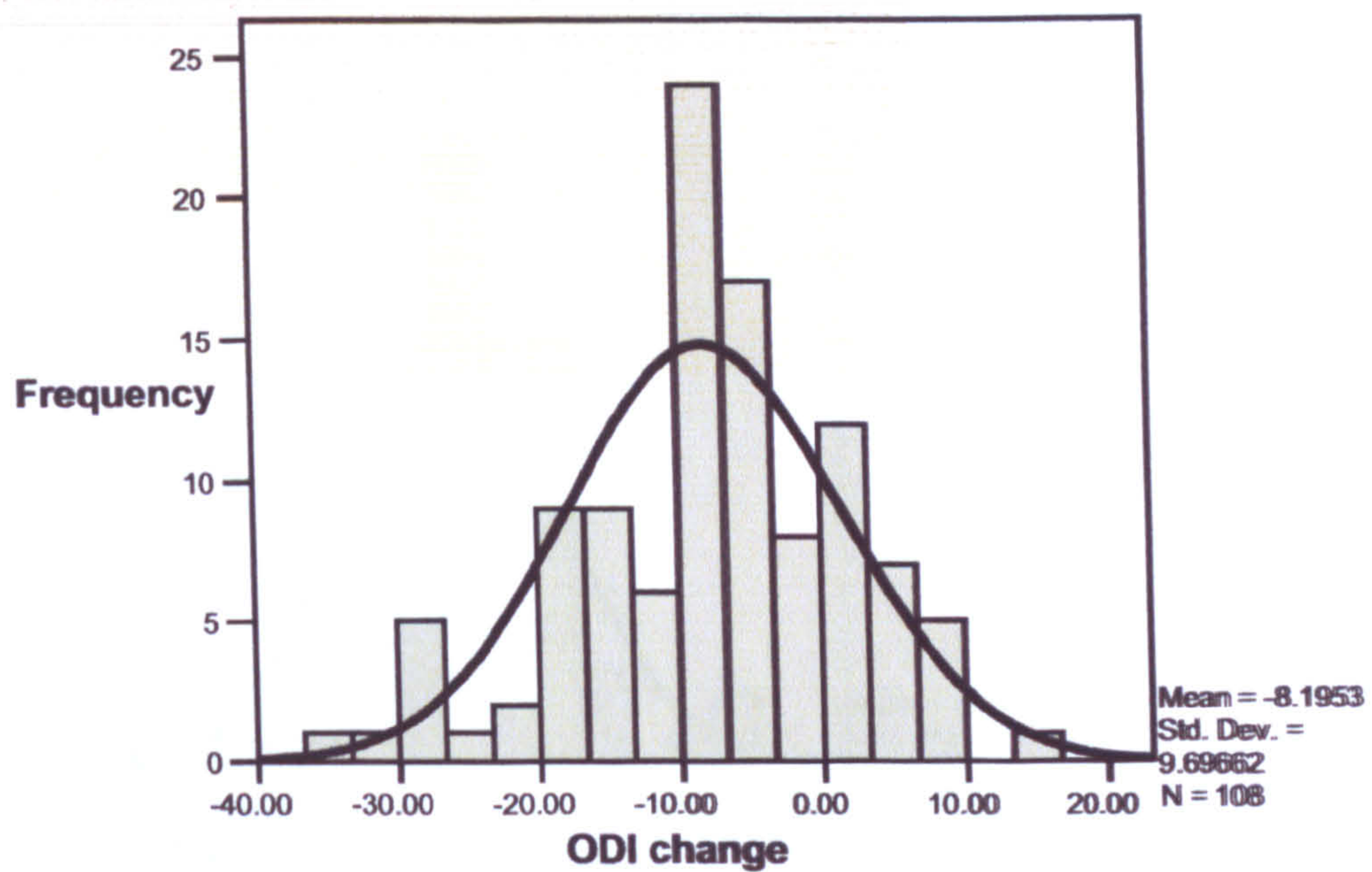


Figure 7. Change in ODI between baseline and 12 months in patients who reported their back pain as better.

* Negative scores =improvement for both the ODI and RMDQ

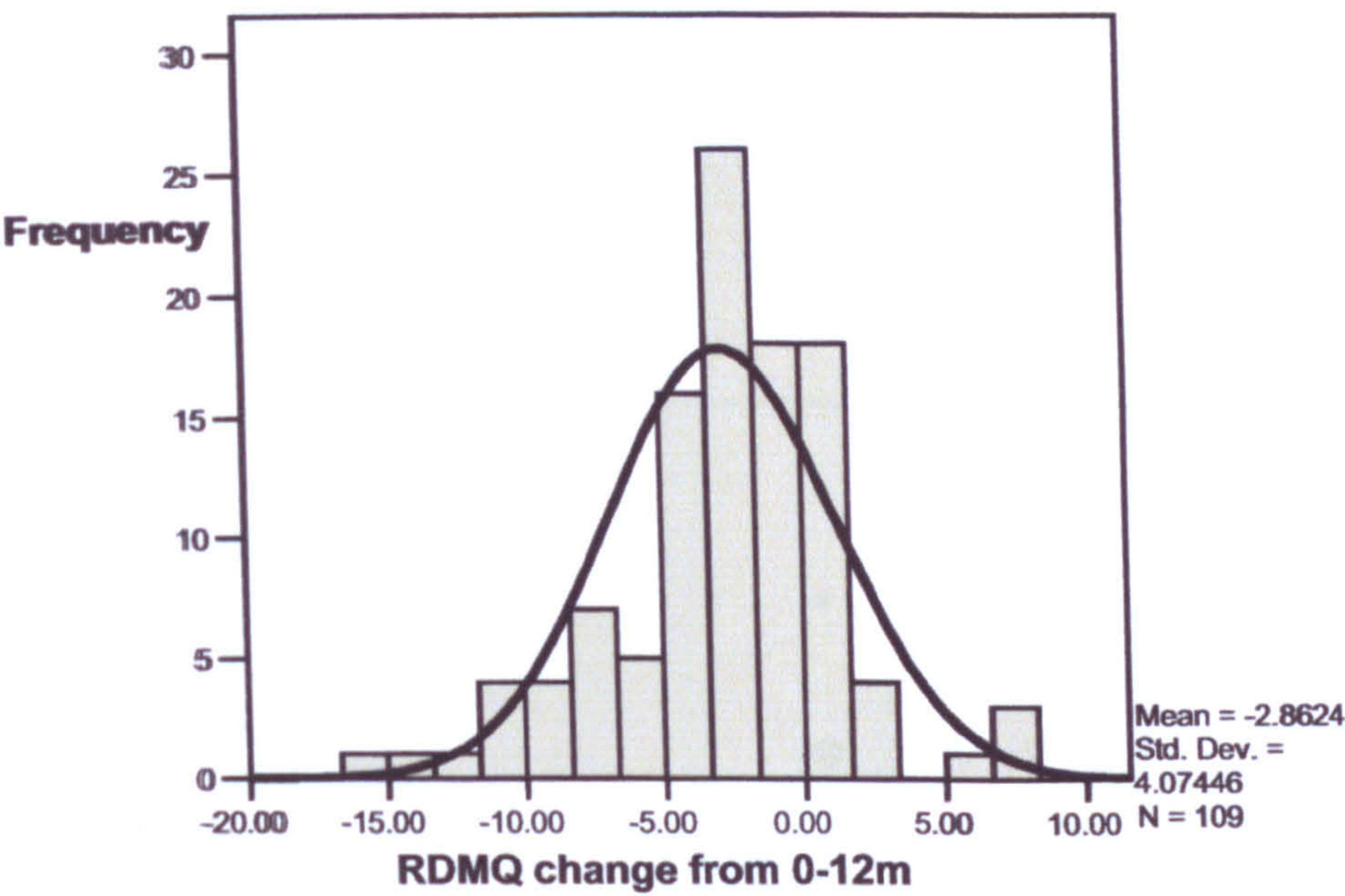


Figure 8. RDMQ change between baseline and 12months in patients who reported their back pain as better

Better		N=109		N=76		Worse		N=16		One way		Post Hoc Test	
Mean (SD)		Median		Same		Mean (SD)		Median		ANOVA			
ODI													
Baseline	18.7 (9.4)	17.8	22.6 (11.6)	20.0	28.0 (12.5)	25.0	F=31.2	p<0.001	p<0.01 for all groups				
12 months	10.2 (9.4)	8.0	22.7 (14.5)	19	37.7 (20.3)	34							
RMDQ													
Baseline	4.9 (3.8)	4.0	6.4 (4.3)	5.0	7.3 (4.5)	5.5	F=19.3	p<0.001	p<0.01 for all groups				
12 months	2.0 (2.7)	1.0	6.1 (5.4)	4.5	10.4 (6.6)	9.0							
PSAQ													
Baseline	4.8 (2.3)	5.2	5.0 (2.2)	5.4	6.1 (1.4)	5.8	F=22.4	p<0.001	P<0.01 for all groups except same and worse				
12 months	1.8 (1.9)	1.1	4.2 (2.3)	4.5	6.5 (1.8)	6.5	p=0.25						

Table 27. Baseline and 12 month scores for the back pain and patient specific instruments in subjects who were better, the same or worse at 12 month follow up

SF-36 Domain	Better N=109		Same N=76		Worse N=16		One way ANOVA		Post Hoc Tukey Test	
	Mean(SD)	Median	Mean (SD)	Median	Mean (SD)	Median	Median		NS=non significant	
Physical function										
Baseline	74.0 (18.1)	80.0	64.4 (24.7)	67.5	59.7 (21.1)	65.0	F=21.6			
12 months	87.6 (13.5)	90.0	65.5 (22.9)	70.0	41.9 (20.9)	42.5	p<0.001			
Role physical										
Baseline	48.8 (40.4)	50.0	42.4 (42.8)	25.0	29.7 (34.4)	12.5	F=13.0			NS Same/worse;
12 months	81.0 (32.6)	100	46.7 (42.1)	50.0	12.5 (18.2)	0	p<0.001			p=.18
Bodily pain										
Baseline	46.3 (19.8)	42.0	44.6 (19.7)	41.0	32.7 (12.2)	31.5	F=31.6			NS Same/worse;
12 months	75.3 (19.8)	74.0	49.3 (19.3)	51.0	27.4 (16.9)	31.0	p<0.001			p=.15
General health										
Baseline	71.5 (17.1)	77.0	64.9 (21.2)	67.0	56.7 (21.1)	53.5	F=4.6			NS Same/ worse
12 months	74.7 (16.7)	77.0	59.4 (21.0)	62.0	49.3 (18.1)	46.0	p<0.01			and worse/better; p= 1,p=.12
Vitality										
Baseline	56.1 (18.8)	55	52.8 (18.7)	55	43.7 (20.2)	47.5	F=12.5			NS Same/worse
12 months	64.0 (19.1)	70	48.9 (20.8)	50	21.1 (20.0)	30.0	P<0.001			p=.16
Social function										
Baseline	76.8 (25.2)	87.5	77.5 (23.8)	87.5	64.1 (30.6)	62.5	F=8.91			NS Same/worse
12 months	89.1 (19.1)	100	77.4 (24.3)	87.5	50.0 (31.9)	50.0	p<0.001			p=.15; better/same p=0.21
Role emotional										
Baseline	72.8 (39.1)	100	73.3 (38.6)	100	68.7 (37.5)	83.3	F=12.8			NS same/worse
12 months	86.6 (29.7)	100	62.9 (45.6)	100	35.4 (39.4)	33.3	p<0.001			group; p=.23
Mental health										
Baseline	72.7 (15.1)	72.0	71.6 (15.5)	76.0	68.3 (14.9)	70.0	F=13.1			NS better/same
12 months	76.4 (16.0)	80.0	68.1 (20.1)	68	51.0 (23.9)	50.0	p<0.001			p=0.02

Table 28. Baseline and 12 month scores for domains of the SF-36 in subjects who were better, the same or worse at the 12 month follow up

EFFECT SIZE, STANDARDISED RESPONSE MEAN (SRM) AND MODIFIED STANDARDISED RESPONSE MEAN (MSRM)

Effect sizes, SRMs and MSRMs were large for the ODI (improved group -0.88 to -1.00) and moderate for the RMDQ (improved group -0.70 to -0.74). Slightly larger values were seen in the improved groups compared with the deteriorated group for both the ODI and RMDQ (Table 29 and 30). The largest values were reported for the bodily pain item of the SF-36 (1.11 to 1.86) and patients specific activity questionnaire (-1.08 to -1.31) in the improved group.

Effect sizes, SRMs and MSRMs, were small across most instruments in the group of patients who reported no change in their back pain state with the exception of the PSAQ (0.35-0.36) and some domains of the SF-36 {bodily pain (0.38), general health (0.25-0.29), role emotional (0.27)}. In this group the smallest effect size was reported in the ODI demonstrating that it was the most specific to change. The ODI and RMDQ appeared to be more responsive to deterioration than the other measures (effect size -0.77, SRM of -0.61, and MSRM of -1.16 for the ODI).

Instrument	Mean score change	SD of baseline	SD of score change	Effect size ¹⁹⁷	SRM ¹⁹⁸ 220	MSRM ²²² 230
ODI#						
Better n=108	-8.32	9.41	9.66	-0.88	-0.86	-1.00
Same n=75	-0.08	11.6	8.35	-0.007	-0.009	-0.01
Worse n=16	9.71	12.5	15.77	0.77	0.61	1.16
RMDQ#						
Better n=109	-2.86	3.83	4.07	-0.74	-0.70	-0.71
Same n=76	-0.30	4.31	4.02	-0.07	-0.07	-0.07
Worse n=16	3.12	4.53	2.5	0.69	1.25	0.78
PSAQ						
Better n=105	3.00	2.29	2.77	1.31	1.08	1.3
Same n=70	0.79	2.17	2.23	0.36	0.35	0.35
Worse n=15	-0.37	1.42	2.22	-0.26	-0.16	-0.16

Table 29. Effect size statistics for back pain and patient specific outcomes at 12months

ODI=Oswestry Disability Index
RMDQ=Roland and Morris Disability questionnaire
PSAQ =Patient Specific Activity questionnaire (difficulty in carrying out activity)
Effect size =mean change score/SD of baseline score
SRM= standardised response mean (mean change score/SD of change scores of the same group)
MSRM=modified standardised response mean (mean change/SD change in stable group)
Negative score on ODI and RMDQ indicate improvement in health

SF-36 domain	Mean change	SD of change	SD of baseline	Effect size ¹⁹⁷	SRM ¹⁹⁸ 220	MSRM ²²² 230
Physical function						
Better n=108	14.28	20.36	18.1	0.81	0.70	0.81
Same n=76	1.82	17.58	24.7	0.07	0.10	0.10
Worse n=16	-17.81	23.38	21.1	-0.84	-0.76	-1.01
Role physical						
Better n=109	32.10	46.79	40.4	0.79	0.69	0.78
Same n=76	4.64	41.1	42.8	0.11	0.11	0.11
Worse n=16	-17.18	42.5	34.4	-0.49	-0.40	-0.41
Bodily pain						
Better n=109	29.56	26.57	19.8	1.49	1.11	1.86
Same n=76	6.11	15.88	19.7	0.05	0.38	0.38
Worse n=16	-5.37	19.03	13.2	-0.40	-0.28	0.34
General health						
Better n=109	2.42	15.77	17.1	0.14	0.15	0.13
Same n=76	-5.28	18.02	21.2	-0.25	-0.29	-0.29
Worse n=16	-7.38	27.57	21.1	-0.34	-0.34	0.40
Vitality						
Better n=109	7.65	16.73	18.8	0.41	0.45	0.42
Same n=76	-2.68	17.92	18.7	-0.14	-0.14	-0.14
Worse n=16	-11.56	18.23	20.2	-0.57	-0.63	-0.64
Social function						
Better n=109	11.18	24.42	25.2	0.44	0.46	0.48
Same n=76	0.69	23.16	23.8	0.03	0.03	0.03
Worse n=16	-14.06	31.25	30.6	-0.46	-0.44	-0.60
Role emotional						
Better n=109	14.38	43.39	39.1	0.37	0.33	0.37
Same n=75	-10.47	38.71	38.6	-0.27	-0.27	-0.27
Worse n=16	-33.33	45.54	37.5	-0.88	-0.73	-0.86
Mental health						
Better n=109	3.30	13.79	15.9	0.24	0.23	0.19
Same n=76	-3.21	16.55	15.5	0.20	-0.19	-0.19
Worse n=16	-17.25	20.17	14.9	-1.15	-0.85	-1.04

Table 30. Effect size statistics for SF-36 domain scores at 12 months.

Receiver-operating characteristic curves

Figures 9 and 10 show the ROC curves produced by comparing sensitivity and 1-specificity at all possible change score cut-off values for improved and non-improved patients who completed the 12 month questionnaires (n=201). Area under the curve (AUC) data for the RMDQ, ODI and SF-36 are shown in Table 31 and 32. The bodily pain domain of the SF-36 produced the highest area under the curve statistics of 0.80 (95% confidence intervals 0.73 to 0.86) followed by the PSAQ and ODI {AUC 0.75 (0.68 to 0.82) and 0.75 (0.68 to 0.82)} respectively. The general health domain of the SF-36 was the least likely to detect change {AUC 0.58 (0.50 to 0.66)}.

Cut-off points for ROC curves

A cut-off point that discriminates best between improved and non-improved patients can be considered when the instrument is to be used to assess individuals in clinical practice. The best cut off is the point on the curve that is closest to the top upper left hand corner of the plot. Assuming that false positive and false negatives are equally important the best cut off points in this study are between -3% to -5% points on the ODI. Inspection of the associated sensitivity and specificity values shows that by using -4.0 as the threshold for improvement, approximately 70% of true positive changes would be correctly classified for the ODI and 34% of stable patients would be incorrectly classified as improving. For the RMDQ an equivalent threshold of -1.5 results in a lower sensitivity value of 60% (chance of detecting true positive

changes) with a specificity value of 36% (chance of incorrectly classifying a patient as improving).

Floor and ceiling effects

On examination of all the trial baseline data (n=286) ninety nine (34.6%) patients scored zero on the role physical dimension of the SF-36 and 67 (23.4%) patients scored 100. One hundred and seventy five patients scored 100 (61.4%) on the role emotional dimension of the SF-36 and 45 patients scored 0 indicating that there was no chance for those patients to report improvement or deterioration on the role emotional domain.

Thirty patients (22%) scored two or less at baseline on the RMDQ including 14 (4.9%) patients who scored 0 (equivalent to no pain or disability). For the ODI, only 16 patients scored less than 8% at baseline (equivalent to a score of two on the RMDQ) including two patients who scored 0.

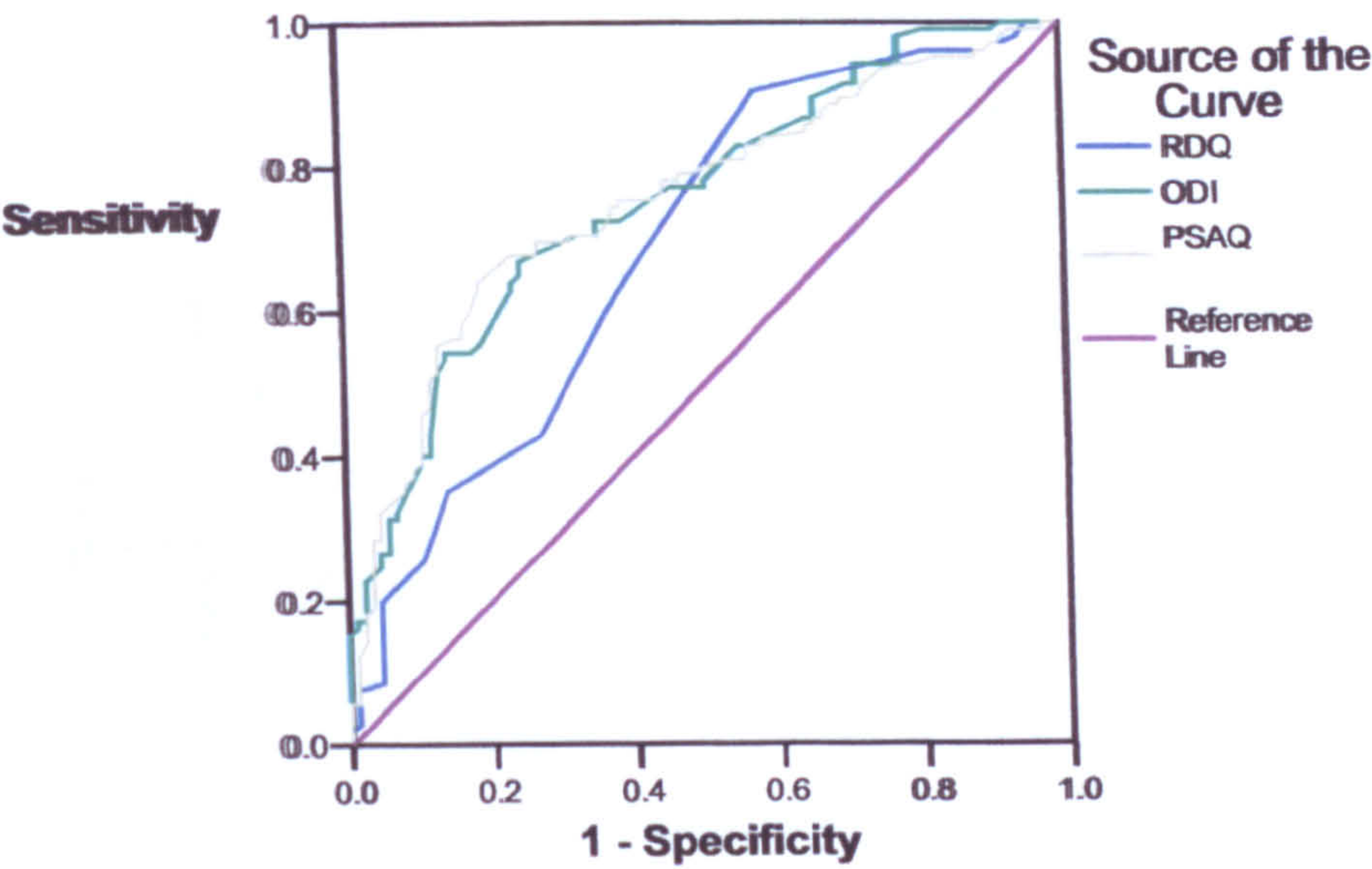


Figure 10. Area under the ROC curve for the ODI, RMDQ and PSAQ at 12 months.

Test Result Variable(s)	Area under ROC curve	95% Confidence Interval	
		Lower Bound	Upper Bound
RMDQ change	.689	.612	.765
ODI change	.752	.684	.820
PSAQ (difficulty) change*	.751	.682	.820

* Values reversed to compare with RMDQ and ODI
 RMDQ= Roland and Morris Disability Questionnaire
 ODI = Oswestry Disability Index
 PSAQ = Patient Specific Activity questionnaire

Table 31. Area under the ROC curve statistics (improved versus non improved) for the RDQ, ODI and PSAQ at 12 months

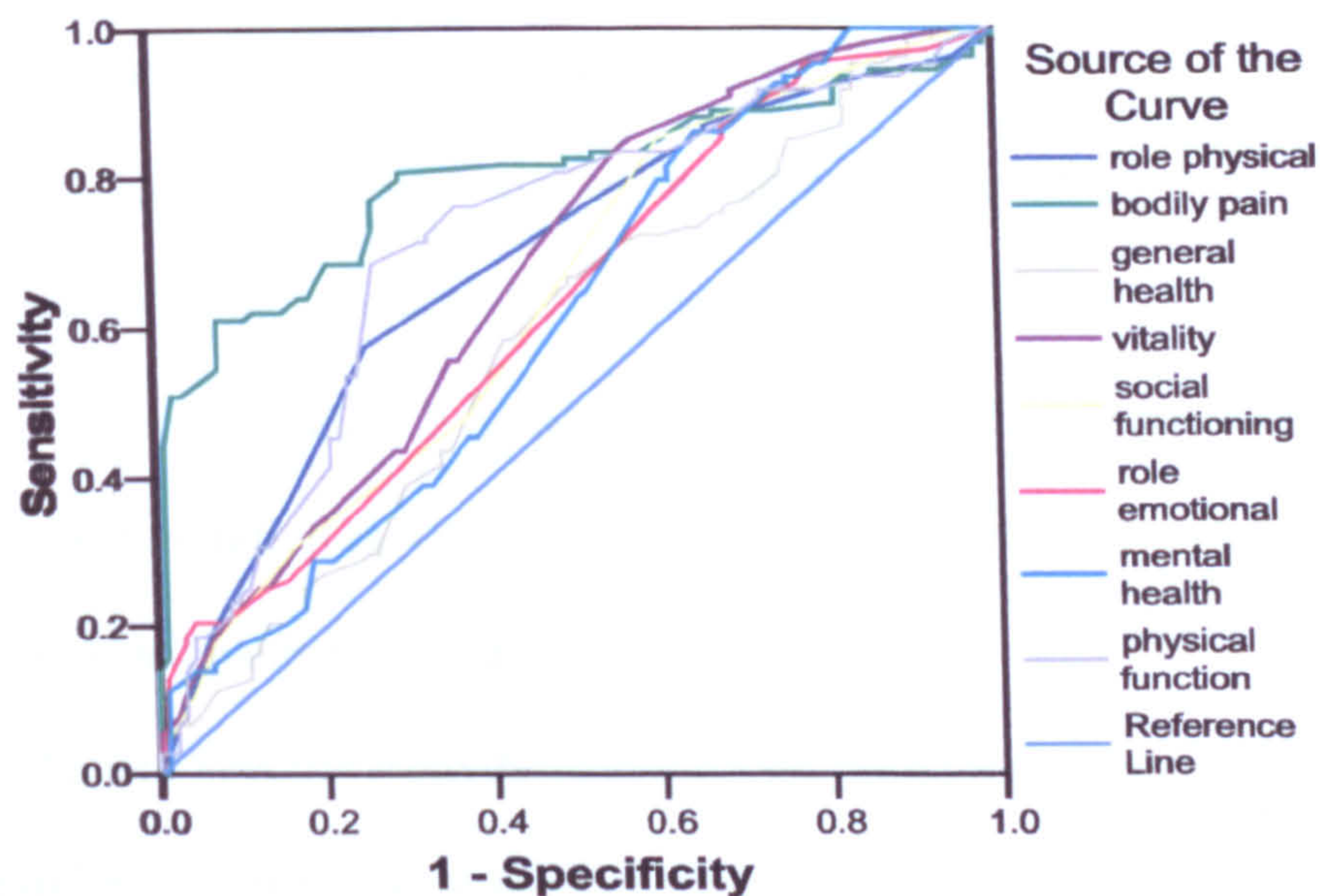


Figure 11. Area under the ROC curve for domains of the SF-36 at 12 months

Test Result Variable(s)	Area under ROC Curve	95% Confidence Interval	
		Lower Bound	Upper Bound
Role physical	.685	.610	.759
Bodily pain	.796	.733	.860
General Health	.584	.504	.664
Vitality	.668	.592	.744
Social Functioning	.634	.557	.712
Role emotional	.627	.550	.704
Mental health	.610	.531	.690
Physical functioning	.708	.634	.782

Table 32. Area under the ROC Curve (improved versus non-improved) for SF-36 domains at 12months

DISCUSSION

This study has shown that the primary outcome used in the trial (ODI) was able to detect improvement as well as deterioration and did not demonstrate floor or ceiling effects. The bodily pain domain of the SF-36 and the PSAQ were the most responsive to improvement but they did not respond as well as the ODI or RMDQ in the deteriorated group. It is an important function of an instrument to be able to detect deterioration as well as improvement but previous research in this field has not included patients who deteriorated.^{209 233 234}

The Patient Specific Activity questionnaire (PSAQ) was used in the trial in this thesis because previous research suggested that it was more able to detect changes that were relevant to patients than the ODI or RDMQ.¹⁷⁰ This study found that while the PSAQ appears to be responsive to improvement it was less specific to change in the group that remained the same and less sensitive to change in the deteriorating groups.¹⁷⁰ This questionnaire was also more time consuming to administer suggesting that overall, it did not have any advantage over the ODI or RMDQ.

The area under the ROC curves (AUC) ranged from (AUC 0.58 (95% confidence interval 0.50 to 0.66) for the general health domain of the SF-36 to 0.80 (95% confidence interval 0.73 to 0.86) for the bodily pain item of the SF-36. Terwee et al (2007) suggest that an AUC statistic of at least 0.70 is necessary to demonstrate that a measure can distinguish patients who have and have not changed according to the external criterion.²³⁷ This level was not reached by the RDMQ and six items of the

SF-36. Overall taking into account the effect size data and the ROC analysis the ODI was the most responsive measure for use in this context.

Comparison with related research

Other authors have concluded that the RMDQ is more responsive to improvement than the ODI.^{185 236 238} This has been consistent for non specific sub-acute²³⁶ and chronic patient groups. However, the studies included patients with higher baseline disability scores than those reported in this thesis.¹⁸⁵ In a group of 76 patients with sub-acute and chronic low back pain Beurskens et al (1996) reported effect size (SRM)¹⁹⁸ and area under the ROC curve statistics for patients with moderate baseline disability scores (RMDQ Mean 11-12; ODI mean 26-29). The largest effect size for the RMDQ (0.93) was reported in the improved group compared with the ODI and PSAQ. In agreement with the study reported in this thesis, Beurskens et al (1996) reported the smallest effect size in the non-improved group suggesting that the ODI was more specific to change.¹⁸⁵

A well conducted Norwegian study including 104 patients with moderately severe acute and chronic low back pain compared responsiveness of the ODI and RMDQ using effect size (SRM) and area under ROC curve statistics. Patients were grouped into improved and unchanged according to a six point global rating scale relating to change in back pain. No differences were found between the ODI and RMDQ for either chronic or acute pain. However, the physical function domain of the SF-36 was less sensitive to change in the chronic group.²¹⁶

In conflict with the results of this study, Roland and Fairbank (2000)¹⁸² recommend the use of the ODI for patients who are likely to have persistent, severe disability and the RDMQ in patients who have relatively little disability. This recommendation is based partly on the study by Beurskens et al (1996)¹⁸⁵ and highlights the need to assess measurement properties of questionnaires in different contexts.

Limitations of the methodology

There is no universal agreement regarding the best statistical approach to measure the magnitude and meaning of change in health status measures.^{214 239} The method for calculating effect size suggested by Guyatt et al (1987)²²² has been criticized for using different sample groups in the denominator and numerator²²⁷ but it also has its advocates.²³² The standard response mean (SRM) takes into account variability in change rather than the baseline score and is favoured by Katz et al 1992.²⁴⁰ Others suggest that no single technique is superior and therefore the three methods were included for comparison with other studies.^{197 198 219 222 230 231}

There are problems with using a global measure of change to assess responsiveness of outcome instruments because there is no gold standard.²⁴¹ In most studies of responsiveness, the reliability and validity of the global measure of change have not been established.^{181 185 215 227} Guyatt et al (2002) raised concerns about validity of global transition rating scales and suggest that a correlation threshold in the region of 0.5, between change in health outcomes and global transition scores, is necessary to assume sufficient validity of both measures.²²⁹ The correlation between the

change in ODI scores and transition rating scale in this study was 0.47 suggesting that both measures were valid in this context.

Norman et al have challenged the use of a single retrospective global measure for three reasons;²²⁷

1. The single item global measure is less reliable and valid than specific and generic measures.
2. Judgement of change is psychologically difficult and therefore suspect.
3. Correlated measurement error between the global rating and the measure under investigation inflates the true association between the ratings.

The authors showed that retrospective global rating of change can result in declaring a measure responsive in a sample of stable patients.²²⁷ In this study the effect size data in the group of patients who reported that they remained the same, were generally small.

The validity of a transitional rating scale is improved by including a number of different categories.²²⁹ Bombardier et al (2000)¹⁷⁷ recommend seven points but in this study only a three point scale was used. The small number of categories on the transition rating scale may have resulted in a less precise measure of change.

The main limitation of this research is the lack of data to assess responsiveness to 'important change'. Determining the amount of change that would signify a clinically important improvement or deterioration on each instrument has therefore not been possible, at the group or individual patient level.

In reality, it is difficult to measure what is clinically important to patients and some clinicians believe it is an unattainable measure.²⁴²

Comparison of generic and back pain specific measures

This study suggested that the back pain specific measures were more responsive overall than the generic measure (SF-36). Some domains of the SF-36 are less likely to perform as well using an external criterion that relates to back pain rather than general health. Campbell et al (2006) used health rather than back pain as an external marker and reported no significant differences between condition-specific and generic instruments in their ability to discriminate between the patients that improved and those that did not.²³³ Similar results were reported by Walsh et al (2003) in a very large sample (n=970) of low back pain patients. Walsh et al (2003) used change in patient's musculoskeletal condition as an external marker and found no difference in responsiveness between generic and condition specific measures.²⁰⁹ Both studies included patients with severe low back pain and in these circumstances other aspects of general health were more likely to be affected. However, some authors conclude that using generic measures alone may be misleading.^{210 234 243 181}

216

Discordance between main trial outcomes and patient perceived benefit

There are several possible explanations for the discordance in this study between the patient perceived benefits, measured on a 0-10 scale, and the main outcomes. A likely explanation is that the patients may have perceived benefits of treatment simply because they enjoyed the experience of therapy regardless of any change in their back pain state and the more treatment they had the more perceived benefit they reported. Additionally, patients can be unduly influenced by their current

health state when they make transition ratings and this can cause considerable bias particularly when there is a large correlation between pre and post test measurements.²²⁹

Outcome instruments need to be able to perform well in the assessment of patients with ongoing disease, when it is likely that conditions remain stable or even deteriorate²³⁴ and for this reason scales that can detect both improvement and deterioration are preferable.

Despite their limitations, many authors regard global transition rating scales as clinically relevant outcome measures.^{177 244} Most clinicians are reluctant to label a patient as improved or deteriorated against a patient's personal assessment.¹⁷⁰

Minimal clinically important change

Important change on the back pain specific questionnaires has been reported by researchers in Canada²²⁶ who investigated responsiveness of the RMDQ in different populations of back pain subjects. They focused on important change in individual patients by calculating ROC curve statistics. A global rating of change was used to classify patients as those who had changed by an important amount and those who had not. Stratford et al (1998)²²⁶ showed that the range of best cut off points for identifying important change on the RMDQ was found to vary from 1 to 8 points depending on the baseline scores of the group studied.

Riddle et al (1998) carried out a similar study to investigate whether responsiveness to change varied depending on the magnitude of the initial RMDQ scores.²²⁵

Important change was based on patient goal achievement and a greater amount of change was required to achieve an important change in patients reporting greater

levels of disability. Two or three points on the RMDQ were proposed as an estimate of important change in individuals with initial scores of less than nine. For patients with particularly low levels of disability (as in this study) a lower cut off was considered to be the best threshold i.e. 2 points. A cut off point is not an exact prediction but frequently reported in the literature to determine minimal clinically important change.^{178 184 185 209 216 220 226 234 236 245} Other researchers have suggested a change of approximately 10%-15% in outcome measures as a threshold for important change.^{216 246 247}

Jordan et al (2006) recommend using a simple rule to identify patients who have a clinically meaningful important improvement by calculating a 30% reduction in score from baseline in combination with a rating of 'better' on a transition rating scale.²⁴⁸ However, Vickers et al (2001) argue that using percentage change from baseline, as an outcome in a controlled trial, is highly sensitive to change in variance and likely to cause bias in the case of baseline imbalance.²⁴⁹ This method should therefore be considered with caution.

Floor and ceiling effects

Floor and ceiling effects on some components of the SF-36 have been reported by other researchers examining the responsiveness of the instrument in the area of low back pain.^{181 216} McHorney and Tarlov 1995²⁵⁰ suggest that health survey instruments with more than 15% of respondents scorings the lowest or highest possible score at baseline should not be used. In the study reported in this thesis, role physical and role emotional domains of the SF-36 suffered floor and ceiling effects making them less responsive to change.

Stratford et al (1996)²⁴⁵ demonstrated that the RMDQ has problems with the scaling at the extremes of range in a group of 60 low back pain patients. They calculated conditional standard errors of measurement for initial and follow-up RMDQ scores, and these values were used to estimate the minimal detectable change. The magnitude of the error was sufficiently small to detect change in patients with initial scores in the central portion of the scale (4-20 RMDQ points). However, the magnitude of the error was too large to detect improvement in patients with scores of less than 4 and deterioration in patients who have scores greater than 20.²⁴⁵ This suggests that the RMDQ should not be used in trials unless patients who report < 4 points on the RMDQ at baseline are excluded. Davidson and Keating (2002)²¹⁵ also reported problems with the scale width of the RMDQ in a study of 106 patients using the same method of calculating minimal detectable change as Stratford et al (1996). They found that 19% of subjects scored less than 4 points at baseline and concluded that the RMDQ would not be able to detect improvement in 51% of their patient sample. In the trial in this thesis, 22% of patients scored less than 2 points on the RMDQ suggesting that this may have reduced the overall responsiveness of the measure in patients who improved. This problem was unlikely to occur on the ODI because very few patients scored at the lower extreme of range at baseline. Stratford et al (1996) found that the ODI had sufficient scale width for clinical application but a change of 10% to 15% points in individual patients would be needed to be 90% confident that a real change had occurred.

CONCLUSION

The data suggests that the ODI was the most responsive outcome for this population of patients. Compared with the RMDQ, PSAQ and SF-36 it was most specific to change, most able to detect deterioration as well as improvement and least likely to be affected by floor or ceiling effects. It therefore appears to have an advantage in scale width for this population of patients. The bodily pain and physical function domain of the SF-36 are useful secondary measures for this group of patients with mild to moderate low back pain. The results of this study provide support for the use of the main outcomes in terms of their ability to detect change at the group level. Additionally, they provide clinicians with an idea of change scores they may expect in a similar group of patients with mild to moderate back pain. However, variability in the outcome scores in those that reported no change in their condition suggest that when used for individual patient assessment larger changes would be needed to be confident that real change had occurred.

Chapter 9

Systematic review of brief bio-psychosocial advice for patients with low back pain

SYNOPSIS

The trial results demonstrated that there were no additional benefits of physiotherapy intervention over and above one session of advice. This led me to investigate the literature that evaluated the effectiveness of brief bio-psychosocial advice (one to two sessions) compared with other treatments for back pain. I chose to carry out a systematic review focusing on the intervention delivered in the trial and used the Cochrane methodology because of its rigorous standard procedure.

BACKGROUND

Information and education is considered to be an important component of management for patients with back pain but the content and type of information varies greatly ranging from simple booklets to website advice. The variability in content is a cause for concern as it can lead to mixed messages and confusion amongst patients. It is widely accepted that re-assurance, advice to remain active and avoidance of bed rest are the most effective methods of managing simple back pain^{12 251} but the evidence for other brief educational advice is unclear. The intensity of educational intervention varies from a multidisciplinary rehabilitation that includes a large component of education to brief face to face sessions with a healthcare professional (1 or 2 sessions only).^{21 252}

Prior to 1980 educational material for back pain was based on medical and mechanical information and focused on restriction of activity and relief of pain.

Research in the 1980-90's suggested that such advice had little long term effect on back pain and rest may have even contributed to the disability caused by it.^{43 45 46} Consideration of bio-psychosocial mechanisms involved in back pain disability have led to the development of different approaches.^{12 46 253 254} The bio-psychosocial model takes account of the person, his or her health condition and the interaction of physical, psychological and social factors in back pain disability.¹² Whilst the physical and psychological components of this model have been well documented in recent years the effect of social factors are still poorly understood.¹²

Back pain beliefs are central to the psychological component of the model because these generally determine behaviour.¹² In particular fear avoidance, which refers to the avoidance of movement or activities based on fear of pain, has been put forward as a central mechanism in the development of chronic low back pain.²⁵⁵ Several authors support the theory that fear-avoidance beliefs may be the most important cognitive factor in the development of chronic disability.^{179 256-258} The fear avoidance model was first described by Lethem et al. in 1983²⁵⁹ as fear of pain and avoidance of movement resulting in perpetuation of pain behaviours (over exaggerated expression of pain through movement or gestures) and experiences even in the absence of demonstrable pathology. Two components of fear avoidance are distinguished; classical and cognitive/operant. The classical component refers to the process in which a neutral stimulus receives a negative meaning. For example, a patient with back pain may develop a fear of exercise after experiencing pain while exercising or after receiving information from a health care professional that

exercise activities can damage the spine. The cognitive model of pain related fear postulates two behavioural responses: confrontation and avoidance and presents possible pathways by which people with back pain get caught in a downward spiral of increasing avoidance, disability and pain or alternatively recover spontaneously. The fear avoidance model is presented in Figure 11. When pain is interpreted as threatening or frightening it can lead to a negative response to recovery and avoidance of activity. Faster recovery is likely to occur for patients without pain related fear as they confront normal daily activities.



Figure 12. The fear avoidance model.

Adapted from Waddell 2004 ¹²(With permission)

This approach focuses on changing beliefs about pain, coping with pain and remaining active, rather than traditional education focusing on pain, providing medical information (anatomy, pathology diagnosis, lifting posture and ergonomics) and encouraging the patient to take a passive role in their management. The differences between the traditional biomedical educational approach and the bio- psychosocial model are summarised in Table 33.

Traditional model	Bio-psychosocial model
Focus on pain	Focus on disability and pain
Impart knowledge	Challenge beliefs and behavior including fear of activity
Provide medical information about anatomy, pathology, diagnosis	Provide information about epidemiology, natural history and prognosis
Instruction on ergonomics, lifting and back specific exercise	Focus on coping with pain
Patient encouraged to be passive recipient of treatment	Focus on staying active, continuing ordinary activity of daily living
	Enable individuals to share and take responsibility for their continued management

Table 33. A comparison of traditional and bio-psychosocial information and advice

Adapted from Waddell 2004¹² (With permission)

The Back Book

The Back Book was developed in conjunction with the RCGP guidelines ⁶⁸ by a group of six back pain specialists. They used information from a back book produced by Roland and Dixon (1989) ²⁶⁰ and a leaflet by Symonds et al (1995). ²⁶¹

The leaflet by Symonds et al. (1995) was the first to introduce the fear avoidance model into back care educational advice. It used the coping and avoidance model to encourage workers to return to work early. In a prospective study Symonds et al (1995) compared factory workers who received a bio-psychological back pain leaflet with a control group of no information or non specific back pamphlet. Those workers who received the bio-psychological leaflet returned to work earlier and showed a positive shift in beliefs about back pain. Developers of the Back Book aimed to change beliefs and behaviour, increase activity and encourage self help.

The Back Book was piloted on patients in an osteopathic setting where patients found the booklet very easy to read, interesting, believable and helpful. ²⁶²

The Back Book has been translated into many languages and used both as an intervention per se and in conjunction with other treatment. ²⁶³⁻²⁶⁵ Its effectiveness alone, in terms of impact on pain disability, work loss and psychosocial factors has not been fully evaluated. Other types of bio-psychosocial educational material have been produced and evaluated in Sweden and the USA. Whilst these adopt a bio-psychosocial approach similar in content to the Back Book they do not attempt to challenge and change dysfunctional beliefs. ²⁶⁶⁻²⁶⁹

METHODS OF REVIEW

Objective

The objective of this review was to determine the effect of brief bio-psychosocial education including written information as defined by Waddell ¹² delivered in no more than two face to face contacts with a health professional for patients with acute, sub-acute or chronic low back pain with or without leg pain.

Inclusion criteria

- Randomised controlled trials were included as they are the gold standard method for evaluating treatment intervention. ¹⁶⁵
- Patients over the age of 17 with acute (up to 3 month history) sub-acute (between 3 and 6 months history) and chronic (more than 6 month history) back pain with or without leg pain.
- Trials with at least one of the following outcomes were included; Pain, disability, general health, work loss or return to work, back pain beliefs or fear avoidance.
- Face to face contact of no more than two sessions (as part of the protocol) with a health care professional offering bio-psychosocial back care education ¹² verbally and in the form of a booklet or pamphlet. This was defined as including all of the following:
 - 1) Reassurance and advice to confront rather than avoid activity (e.g. lifting, sitting bending)
 - 2) Focus on addressing beliefs about pain and behaviour

3) Advice to cope with pain and exacerbation of symptoms.

Exclusion criteria

Interventions including group educational sessions, those including advice to exercise only; trials including a bio-psychosocial back care booklet in the comparison arm; trials that sent the educational booklet/pamphlet by post (no face to face contact); trials including more than two sessions of education as part of the protocol; trials in which back pain education was not the main component of the face to face contact; Non-randomised controlled studies.

Search strategy for identification of studies

Relevant studies were identified using computerised search strategies in the following databases;

The Cochrane controlled trial register (CCTR)

Current controlled trials database (<http://controlled-trials.com>)

Ovid MEDLINE (1966 to May 2006)

EMBASE (1988 to May 2006)

CINAHL (Cumulative Index to nursing and allied health 1982 to May 2006)

PsycInfo (1985 to May 2006)

ISI Web of knowledge-Web of science; science citation index (Sci-expanded 1970-May 2006) and Social science citation index (SSCI 1970 to May 2006)

PEDro (physiotherapy evidence database) using the following search fields

(Abstract-back pain; Therapy-education; Problem-pain; Bodypart-lumbar spine /sacroiliac or pelvis; subject- musculoskeletal.

The highly sensitive RCT search strategy published by Dickersin (1994)²⁷⁰ was run together with terms specified to search for low back pain and brief intervention advice. The search strategy for Ovid MEDLINE is shown in Appendix 8. This strategy was adapted for EMBASE and PsycINFO and CINAHL.

A hand search of reference lists in relevant publications and reviews was carried out along with citation tracking using Web of Science. Personal communication with authors of The Back Book, one author of an unpublished RCT and one author of an included RCT was necessary to clarify methodology.

Publication selection

One reviewer independently carried out the search, selected relevant titles and abstracts and identified papers that met the inclusion criteria (HF). Two reviewers independently assessed the quality of the trials (HF and HS) using the scale developed by Jaded 1996⁸⁵ and adapted by Van Tulder (2003)⁹⁰ for use in trials of physiotherapy and exercise. The criteria for the validated scale are presented in Box 1 in Chapter 3 and Appendix 9. The criteria have the following advantages:

1. It assesses allocation concealment which has been clearly shown to be associated with exaggerated treatment effects.
2. It is the only scale to be evaluated for discrimination, reliability and construct validity.

Data extraction

Data was extracted using the forms reproduced in Appendix 10. If data were missing further details were requested by email. Data extraction was blind for one of the reviewers only as the papers were already familiar to HF.

Data analysis

None of the data was suitable for pooling because the interventions included in the studies were not comparable. For comparisons of outcomes in the individual trial the mean differences were calculated for continuous outcomes and relative risk and odds ratio for the dichotomous data. All analysis was carried out using REVMAN manager 4.2.

Methodological quality of included studies

The methodological quality was assessed using levels of evidence described by van Tulder (2003) taking into account the participants, interventions, controls, outcomes and methodological quality of the studies.⁹⁰

The levels of evidence were categorised as;

Strong: consistent findings among multiple high quality RCTs

Moderate: consistent findings in one high level RCT and one or more low quality RCT or generally consistent findings in multiple low quality RCTs

Limited or conflicting evidence: only one RCT (high or low) or consistent findings in low quality trials

No evidence: No evidence from trials or no RCTs

High quality studies were defined as RCTs which fulfilled 6 or more of the validity criteria.

Clinical relevance

The clinical relevance of the study intervention was independently assessed by two reviewers using questions recommended by the Cochrane Back Review Group.⁹⁰

Description of studies

The Medline search identified 129 papers, CINAHL 72 papers, PschcINFO 11 and PEDRO 146 papers. The title and abstracts of these papers were reviewed and 21 full papers of randomised controlled trials were extracted. In most cases it was not clear from the abstract what type of education intervention was used. The papers included one follow up trial and one trial that reported outcomes in two separate

publications. Two trials with a total of 476 patients were included in the review (see Table 34). Sixteen trials were excluded for the following reasons; Traditional back education booklets or pamphlets were used as part of the intervention in ten trials. The educational content of these booklets are described in Table 35^{148 260 267 271-277}. The Back Book was used in both arms of the study in six studies^{263 265 278-282}. All the reasons for exclusion are reported in Table 36. One abstract of a trial including 2752 patients was identified but remained unpublished by February 2007. (Table 37) Further information was not made available by the author following personnel communication. The two studies included in the review were carried out in the UK and Netherlands. Both studies included patients with acute or sub acute low back pain (< 12weeks duration).

Interventions

The Back Book versus traditional back care information.

Burton et al (1999) compared The Back Book with a traditional back booklet (Handy Hints). Patients were seen by either general practitioners (GPs) or osteopath⁴³. Additional intervention included general re-assurance and advice for both groups and those seen by the GENERAL PRACTITIONER were also given sick certification and analgesic where appropriate. Additional manipulative therapy was given to 29 patients treated by the osteopaths (mean 4.3 sessions).

The Back Book (with brief intervention strategy) versus usual General Practitioner care.

Jellema et al.(2005)²⁸³ compared an intervention strategy delivered by general practitioners lasting 20 minutes with usual GP care. The intervention included an

exploration phase where the GP explored psychological prognostic factors including patient's own ideas about low back pain, fear-avoidance beliefs, worries about back pain, catastrophising thoughts (feeling that pain will never stop), pain behaviour, reaction of family to low back pain and physical and psychological factors at work. The second phase used information gained in the exploration phase to educate the patient and in the third phase patients were given a booklet based on The Back Book. The usual care group followed the Dutch guidelines for GPs including reassurance, advice and analgesics.

Outcome measures reported

Both studies reported disability measured on the Roland and Morris disability questionnaire (RMDQ) ¹⁸³ and pain measured as usual pain, worst pain or best pain on a 0-100 visual analogue scale ⁴³ and pain on the day (0-10 VAS).²⁸³ Burton et al (1999) used fear avoidance beliefs ²⁸⁴ as the primary outcome. In addition they measured beliefs about the inevitable consequence of back pain using the back beliefs questionnaire.²⁸⁵ Jellema et al. (2005) reported disability using the RMDQ,¹⁸² the general health question of the SF-36 (How is your health in general compared to 1 year ago?),²⁸⁶ perceived recovery and sick leave as the primary outcome and included fear avoidance beliefs, catastrophising thoughts measured using the coping strategies questionnaire ²⁸⁷ and distress as baseline data only.

RESULTS

The two included trials were clinically heterogeneous as one compared two different back care booklets and one compared a booklet and psychological assessment with usual care. Therefore it was not possible to calculate overall effects. Both trials were of high methodological quality scoring 7/10 (Burton) and 6/10 Jellema. (See Tables 38 and 39). The trial by Burton et al. (1999) scored higher due to the double blind methodology but had a high loss to follow up. Both included interventions that were recommended in clinical guidelines ¹¹ and scored 4/5 for clinical relevance (Table 40). Adequate statistical analysis were used including analysis of sample mean, analysis of repeated measures, and assessment of relative risk (RR). ^{165 288} Both studies reported sensitivity analyses to account for missing data.

Disability. No statistically significant differences in disability (RMDQ) were seen between groups at any time in either study. Burton et al (1999) reported significant improvements in disability scores in both groups over time. Jellema et al (2005) reported a non significant mean difference between groups of 0.25 over the 12 month period (95% confidence interval -0.77 to 1.28).

Pain. No statistically significant differences were reported between groups in any of the pain scores in either study. The mean difference in worst pain during the day reported by Burton (1996) was -0.90 (95% confidence interval -11.45 to 9.65) at 3 months and 0.10 (95% confidence interval -9.92 to 10.12) at 12 months (Figure 12). The mean difference in pain severity over the 12 month period during the day in the study by Jellema et al. (2005) was 0.015 (95% confidence interval -0.41 to 0.44) on a 0-10 scale.

Fear avoidance beliefs. Statistically significant differences were found between groups in self reported fear avoidance beliefs in the trial by Burton et al (1999) in favour of the bio-psychosocial approach. Relative risk analyses were 2.72 (95% confidence interval 1.57 to 4.72) at 2 weeks, 1.53 (95% confidence interval 1.05 to 2.23) at 3 months and 1.47 (1.02 to 2.11) at 12 months (See Figure 13). Fear avoidance was only reported as a baseline measure in the study by Jellema et al. (2005).

Sick leave and perceived recovery. Neither work loss nor sick leave was measured by Burton et al. (1999). In the trial by Jellema et al. (2005) no significant differences were seen between groups over time for sick leave (odds ratio 0.69 (95% confidence interval 0.43 to 1.13 or patient perceived recovery (odds ratio 1.16 (95% confidence interval 0.63 to 2.17) Odds ratio > 1 means that more patients in the brief intervention group reported sick leave or no recovery (Figure14). Jellema et al. (2005)²⁸³ reported no significant difference between groups in perceived general health (mean differences over the 12 month period 0.056 (95% confidence interval -0.07 to 0.17). The mean differences at 3 and 12 months were 0.0 (95% confidence interval -0.18 to 0.18) and 0 (95% confidence interval -0.20 to 0.20) respectively (Figure 15).

Figure 13. Mean differences for worst pain during the day at 3 and 12 months comparing The Back Book versus a traditional booklet

Review: Minimal back care intervention (Version 02)
Comparison: 01 Back book versus traditional back advice
Outcome: 01 Pain scores (0-100: worst pain =100; 0=no pain) Worst pain during day

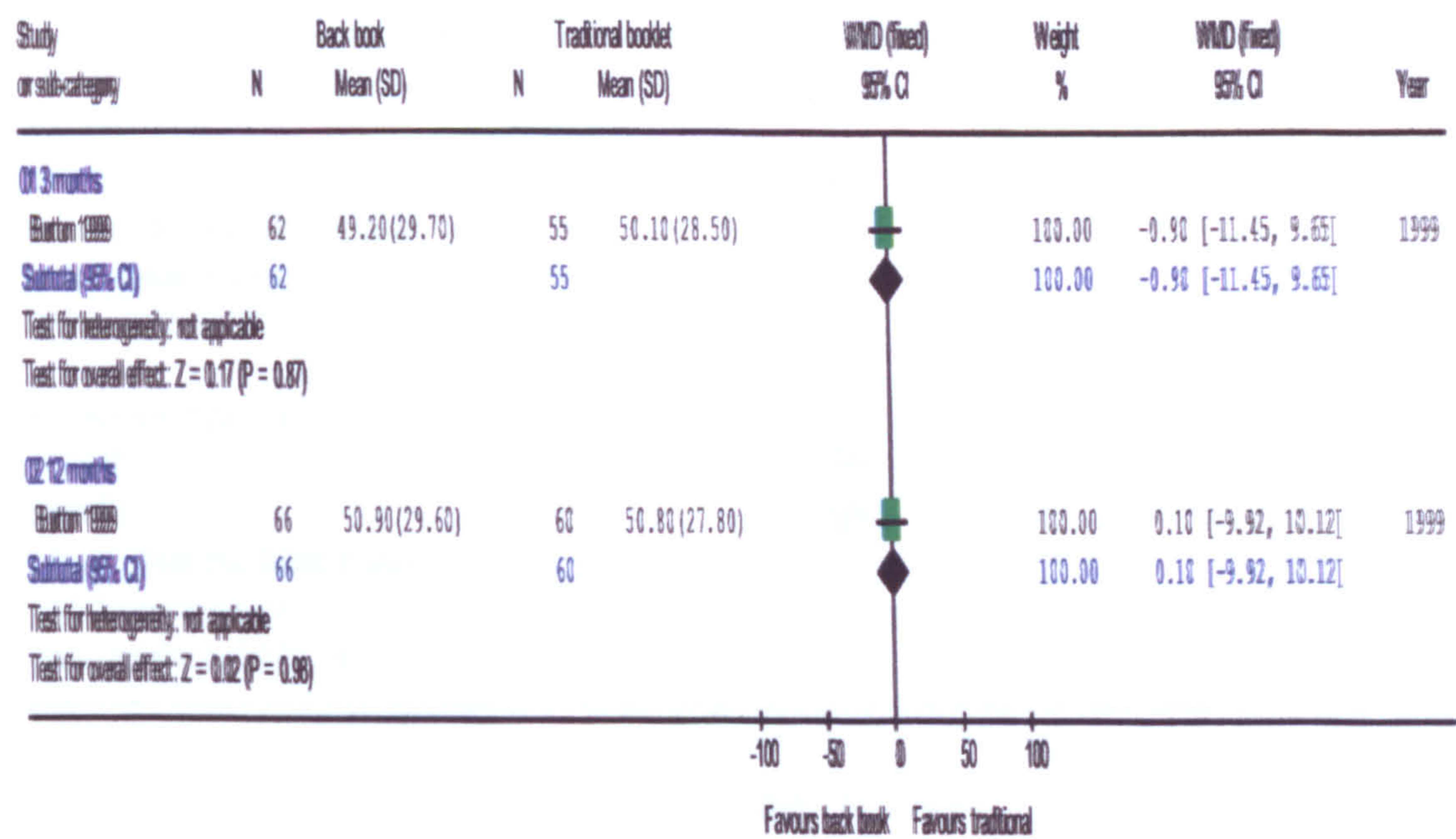


Figure 14. Relative risk for fear avoidance beliefs at 3 and 12 months comparing The Back Book versus a traditional booklet

Review: Minimal back care intervention (Version 02)
Comparison: 01 Back book versus traditional back advice
Outcome: 02 Clinically important improvement in FabPhys (>4 point reduction) at 3 months

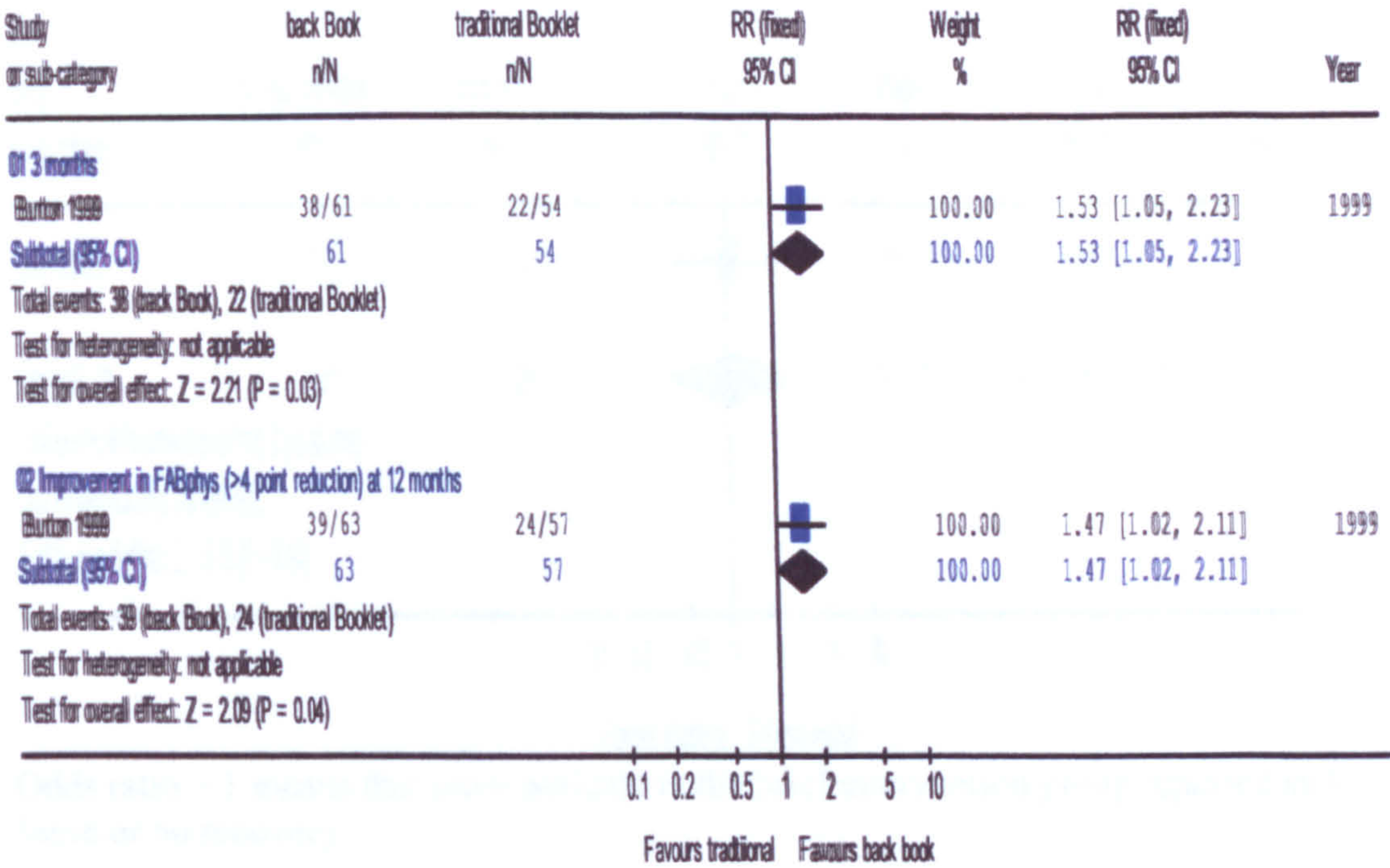
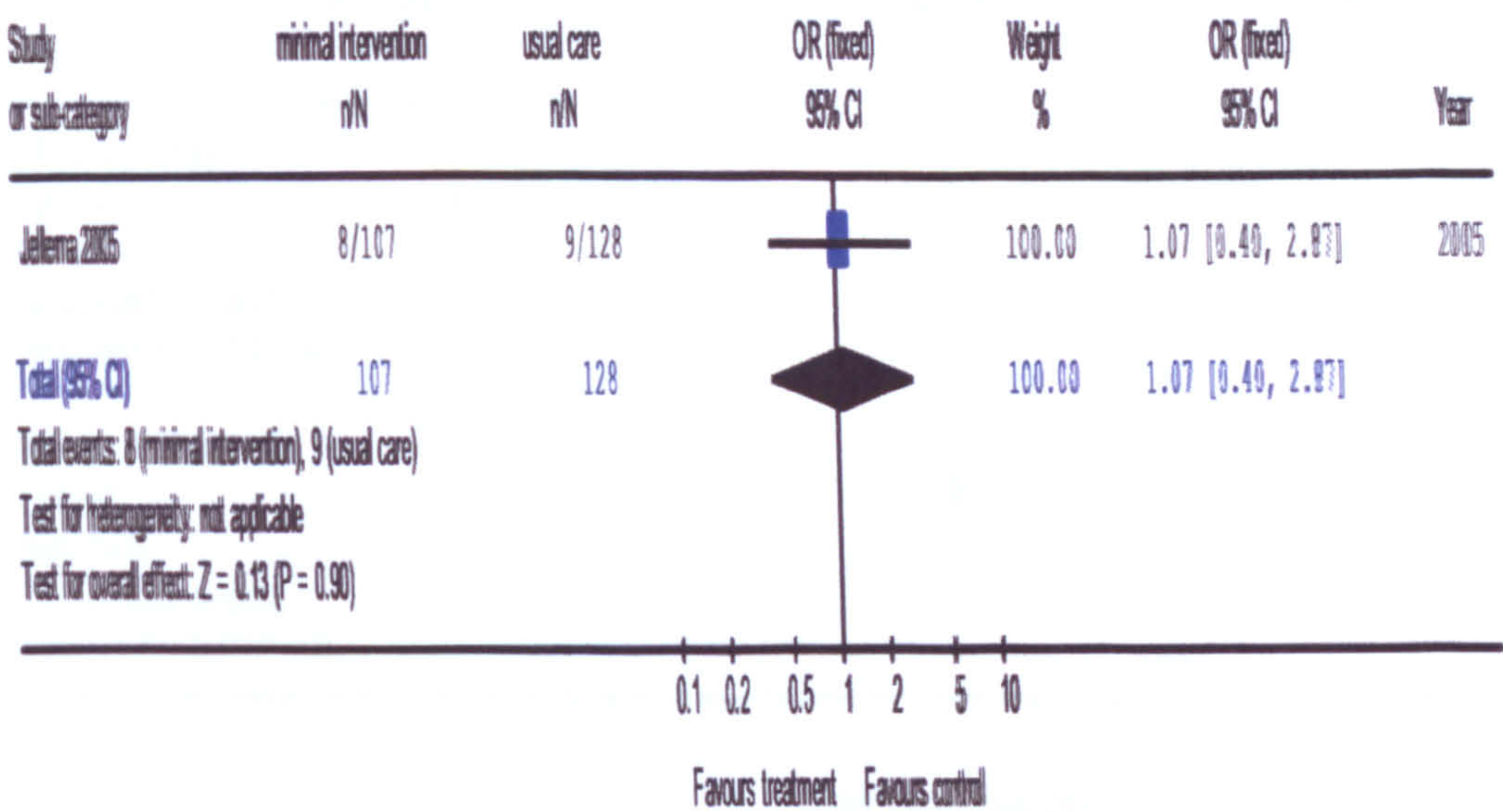


Figure 15. Odds ratio for sick leave due to back pain at 12 months comparing brief intervention treatment (treatment) versus usual care (control)

Review: Minimal back care intervention (Version 02)
Comparison: 02 back book Vs usual care
Outcome: 03 Sick leave because of back pain at 12 months



Odds ratio > 1 means that more patients in the brief intervention group reported sick leave or no recovery

Figure 16 Mean differences for general health scores (sub-item of SF-36 scored 1-5) at 3 and 12 months comparing brief intervention treatment (treatment) versus usual care (control)

Review: Minimal back care intervention (Version 02)
Comparison: 02 back book Vs usual care
Outcome: 04 General health scores (1-5)

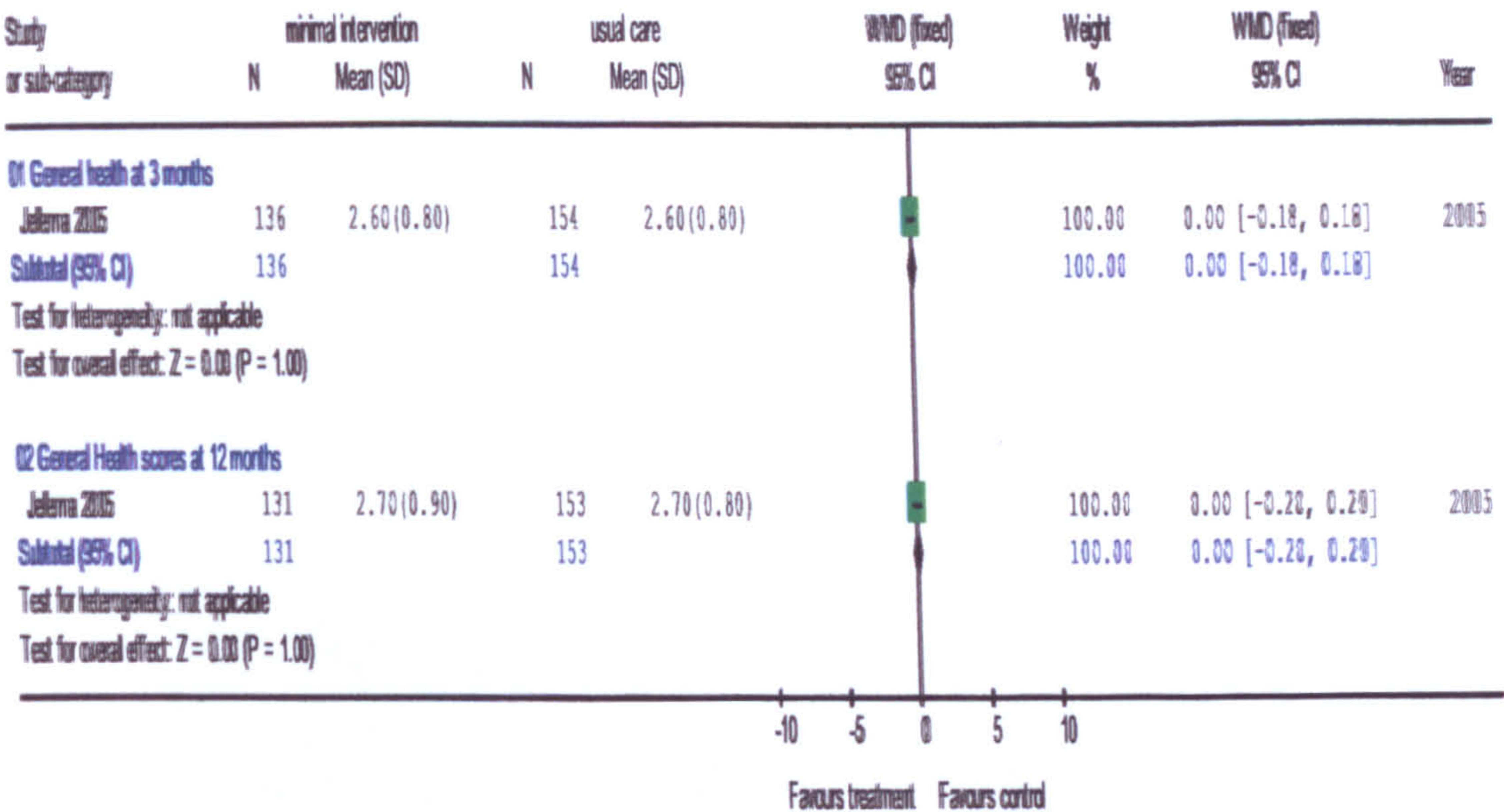


Table 34. Characteristics of included studies

Study	Methods	Participants	Interventions	Outcomes	Notes
Burton 1999	Double-blind randomised controlled trial	162 patients based in 5 NHS general practices and one private osteopathy practice; inclusion criteria: 17 to 70 years old, acute or recurrent nonspecific low back pain with or without referred leg pain; < three months duration, no loss of work or any other health care in the last 3 months. English as the patients native language; Exclusion criteria; serious pathology or nerve root pain, unable to read and write; primary psychiatric illness, history of alcohol or drug abuse.	Back book versus a back booklet based on traditional advice. Back education provided by 5 primary care practices and one private osteopathy clinic. Patients randomised to either receive The Back Book or a back booklet based on traditional advice. Patients seen by GPs were given re-assurance and advice together with sick certification and analgesic where appropriate. Patients seen by the Osteopaths were given similar advice as well as a number of sessions of manipulative therapy.	Primary outcome; Fear avoidance beliefs questionnaire, other treatments received. Secondary outcomes; back beliefs Questionnaire which measures beliefs about the inevitable consequences of back trouble; the RMDQ, VAS of 'usual pain', 'at worst' and 'at best'	GHQ used as baseline variable to account for differences in psychological stress

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Jellema 2005	Cluster randomised controlled trial. Randomisation carried out at the GP level.	314 patients with acute and sub-acute low back pain of <12 weeks or exacerbation of persisting low back pain. Aged 18-65 years old, sufficient knowledge of the Dutch language. Exclusion; LBP caused by specific pathological conditions or currently being treated by another health care practitioner or pregnancy.	Intervention included information and advice based on The Back Book given in a single session (20 minutes). In addition psychological prognostic factors were explored. The control group received usual care from their GP.	Primary outcome; RMDQ measured at baseline, 6, 13, 26 and 52 weeks. Perceived recovery measured on a 7 point likert scale, sick leave because of low back pain; severity of pain during the day (0- 10) and perceived general health. Fear avoidance beliefs, catastrophising thoughts and distress were measured at baseline only.	
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ODI = Oswestry Disability Index
 RMDQ = Roland and Morris Disability Questionnaire
 PMP = pain management programme
 GP = General Practitioner
 VAS = Visual Analogue scale

Table 35. Type of education material in excluded studies

Study	Type of education
BEAM 2004 ²⁶³	The Back Book
Cherkin 1996 ¹⁴⁸	‘Back in Action; A guide to understanding your low back pain and learning what you can do about it.’ A booklet that discussed causes of back pain, prognosis, appropriate use of imaging studies and specialists. It emphasized the value of returning to normal activities and encouraged gradual increase in exercise such as walking, swimming and riding a stationary bicycle. The booklet encouraged adoption of exercise goals and included a log for recording daily progress.
Cherkin 1998 ²⁷⁵	. ‘Back in Action’ booklet
Cherkin 2001 ²⁷⁶	The Back Pain Help Book was used along with 2 video -tapes (1 on self management and 1 on exercise). The booklet included information about back pain and its treatment, techniques for controlling and preventing pain and for improving quality of life, suggestions for coping with the emotional and interpersonal problems. ²⁸⁹
Frost 2003 ²⁷⁸	The Back Book
Hazard 2000 ²⁶⁶	‘Good News About Back Pain’ pamphlet included information from 3 sources; 1) ‘Understanding Acute Low Back Pain’ from the Agency for Health Care Policy and Research; 2) ‘Back in Action’ developed by Cherkin et al. ²⁷⁵ ; 3) ‘Back Pain-Don’t suffer Needlessly’ by Symonds et al. ²⁸⁵ . The final draft was edited by The authors of The Back Book. It focused on positive behavioural and attitudinal impact with a central goal of encouraging self-care and quick return to work activities.
Hurley 2004 ²⁷⁹	The Back Book.
Koumantakis 2005 ²⁸¹	The Back Book
Linton 2000 ²⁶⁷	The back care pamphlet provided straightforward advice about the best way to cope with back pain. It was based on preventing fear avoidance, promoting coping and staying active. The reader was encouraged to confront rather than avoid activities. The booklet was developed by Symonds et al. ²⁸⁵

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Little 2001 ²⁷¹	The Back Home Booklet. The booklet gave a positive message about recovery from back pain. In addition it included information on; Anatomy and causes of back pain; An active self help approach to back pain encouraging patients to identify position that are painful and positions to ease pain; Advice to minimize bed rest, keep mobile and increase walking time each day; Practical tips on getting about , moving, bracing when coughing, driving and how to lift; Exercise advice and further reading (Treat your own back by Mackenzie)
Niemisto 2003 ^{273 290}	The Back Triumph. ²⁹¹ A 25 page traditional back booklet including basic anatomy and physiology of the spine, ergonomics, exercise advice and education on how to cope with an acute episode.
Roberts 2002 ²⁷²	Back Home leaflet. The leaflet included practical hints on how to deal with back pain. It also includes simple anatomy, advice on limited use of radiographs, simple messages about mattresses, information about analgesia, the need to reduce bed rest and importance of keeping active. Advice on sitting and ergonomics. Emphasis placed on self help.
Roland 1989 ²⁶⁰	A traditionally based back booklet including advice to rest , brief account of the anatomy of the spine, practical advice on activities and back specific exercises. Emphasis placed on self care.
Sherman 2005 ²⁷⁷	'The Back Pain Help book. An evidence based book that emphasized self-care strategies such as adoption of fitness and strength programmes, appropriate lifestyle modification and guidelines for managing flare-ups.
Wand 2004 ²⁶⁵	The Back Book
Wright 2005 ²⁸⁰	The Back Book

Table 36. Characteristics of excluded studies

Study	Reason for exclusion
BEAM 2004	1334 patients in a pragmatic multi-centre randomised controlled trial. Intervention included best care delivered by GPs, exercise in the form of physical fitness programme and manipulative therapy. (Reason for exclusion; The Back Book was included in all arms of the trial)
Cherkin 1996	293 patients recruited in a RCT aiming to evaluate educational intervention. Patients were randomly allocated to receive usual care, an educational booklet or a 15 minute session with a clinical nurse specialist. The educational booklet was 'Back in Action' and emphasised the value returning to normal activities and encouraged gradual increase in exercise. Authors concluded no impact of educational booklet on symptoms, function, disability or health care.(Reason for exclusion; not bio-psychosocial education)
Cherkin 1998	321 patients randomly assigned to physical therapy with McKenzie therapists, chiropractic treatment or brief intervention including an educational booklet. Limited benefit of physical therapy over educational intervention. (Reason for exclusion; not bio-psychosocial education).
Cherkin 2001	RCT including 262 patients randomly assigned to receive acupuncture, therapeutic massage and a self care education for back pain. The booklet was delivered along with 2 video -tapes (1 on self management and 1 on exercise). At 1 year, there was no difference between the groups in reducing pain and disability. (Reason for exclusion; Co-intervention included as part of the protocol and not bio-psychosocial education).
Frost 2003	286 patients recruited in a pragmatic multi-centre parallel randomised controlled trial including patients with sub-acute and chronic low back pain. Physiotherapy intervention in the form of manual therapy and exercise compared with advice given by a physiotherapist. The Back Book was given to both groups (Reason for exclusion; bio-psychosocial education used as intervention in both arms of the trial)
Hazard 2000 ²⁶⁶	486 occupational workers with acute back pain were included in a RCT using block randomization. A pamphlet stressing psychological recovery issues with an aim to encouraging self care, activity and quick return to work was compared with a control of no pamphlet. Pamphlets were mailed to half of the participants and no other interventions were included. There were no differences between groups in pain, health care visits or work absence. (Reasons for exclusion; Pamphlet was based on psychological issues and edited by the authors of The Back Book but the intervention was sent by post rather than in a face to face session)

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Hurley 2004 ²⁷⁹	240 patients randomised in an RCT aiming to investigate the differences in effectiveness of manipulative therapy, interferential therapy or a combination of the 2 treatments. All groups received a copy of The Back Book. No difference found between groups (Reason for exclusion: co-intervention included as part of the protocol and not bio-psychosocial education)
Koumantakis 2005 ²⁸¹	55 patients recruited in a RCT comparing specific stabilising exercises to general back exercises. Both groups received The Back Book. Subjective measures of disability and pain reported and no difference found between groups (Reason for exclusion; The Back Book used in both treatment arms)
Koumantakis 2005 ²⁸²	RCT as above reporting physiological muscle measurements and function. No difference found between groups (Reason for exclusion; The Back Book used in both treatment arms)
Linton 2000 ²⁶⁷	243 patients with acute or sub-acute back pain were included in a RCT compared two different types of education information with a cognitive behavioural programme for patients with acute and sub-acute LBP. The back care pamphlet was based on preventing fear avoidance, promoting coping and staying active. Cognitive behavioural group reduced the risk of long term disability compared with pamphlet group (Reason for exclusion; no face to face contact with health care practitioner in the educational information group)
Little 2001 ²⁷¹	RCT factorial design including 311 patients with a new episode of back pain. Patients were randomised to either receive a self management booklet, advice to take regular exercise, both or neither. Small benefits were found for both booklet and advice groups at 1 and 3 weeks follow up in satisfaction but no additional benefit of receiving both. (Reason for exclusion; not bio-psychosocial education).
Niemisto 2003 ²⁹⁰	RCT including 204 patients with chronic low back pain randomised to either manipulative therapy or a brief intervention group including 2 one hour sessions and a traditional back booklet. (Reason for exclusion; not bio-psychosocial education)

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Niemisto 2005 ²⁷⁴	RCT long term follow up of trial (Niemisto 2003) including 204 patients with CLBP. Combined treatment was only slightly more effective for reducing pain compared to physician consultation and a booklet alone. Physician consultation alone was more cost-effective for both health care use and work absenteeism, and led to equal improvement in disability and health-related quality of life. (Reason for exclusion ; not bio-psychosocial education)
Roberts 2002 ²⁷²	64 patients with acute low back pain recruited in a single blind randomised controlled trial. The aim was to test the effectiveness of patient information leaflets on knowledge, attitude, behaviour and function. Intervention included GP usual care and advice for back pain or GP usual care + a back home leaflet and verbal re-enforcement of the contents. The leaflet included practical hints on how to deal with back. Back education can change aspects of knowledge and behaviour. (Reason for exclusion: not bio-psychosocial education)
Roland 1989 ²⁶⁰	Small RCT of mixed population of primary care patients. Randomisation was based on date of birth and was not concealed. The traditional back booklet was compared with usual care for GPs. Booklet group had some effect on in altering knowledge and behaviour. Significantly fewer patients in booklet group consulted for their back pain over a 1 year period (reason for exclusion; not bio-psychosocial education)
Sherman 2005 ²⁷⁷	RCT including 101 patients with chronic low back pain. Patients were randomised to receive yoga, exercise or a self care booklet 'The Back Pain Help book'. Yoga was found to be more effective than exercise and the booklet. (Reason for exclusion; not bio-psychosocial education)
Wand 2004 ²⁶⁵	Single blind RCT including 102 patients with acute LBP of cross over design comparing advice given by a physiotherapist and bio-psychosocial intervention, manual therapy, and exercise. Short term results found intervention to be more effective than advice and Back Book. The timing of treatment was also evaluated. (Reasons for exclusion 'The Back Book' was used in both arms of the study)
Wright 2005 ²⁸⁰	RCT including 119 patients with a new episode of LBP. The Back Book was used in both treatment arms in addition to either one session of advice given by a GP and practical advice on how to modify physical activities specific to the individual's work situation or assessment and treatment by a physiotherapist +group exercise sessions. Results suggest that the costs of the back programme are more than reimbursed as a consequence of earlier return to work(Reason for exclusion; The back Book used in both arms of the study)

LBP = low back pain

RCT = randomised controlled trial

Table 37. Characteristics of ongoing study

Study	Trial name or title	Participants	Interventions	Outcomes	Results	Notes
Coudeyre (2005) ²⁹²	Impact of The Back Book on acute low back pain	2727 patients with acute low back pain	Advice book (The Back Book) and usual oral information or oral information alone	Persistent back pain 3 months after baseline intervention; pain intensity; perceived handicap and disability (Quebec scale) LBP beliefs (FABQ)	2337 patients (85.7%) were assessed at follow. Intervention group reported persistent pain less often at 3 months. (10.5% Vs 14.1% p=0.007).	Presented at ISSLS New York May 2005

LBP = low back pain

Criteria	Burton et al	Notes
1. Randomisation	SATISFIED	Previously generated random list in each primary practice
2. Concealment	SATISFIED	Sealed and unmarked envelope
3. Drop out rate	Not satisfied	23% at 2 weeks, 27% at 3 months and 22% at 1 year
4. Co-intervention avoided	Not satisfied	Co-intervention not avoided in protocol and comparability not documented
5. Patient blinded	SATISFIED	Patients were not aware of the 2 different booklets although this was not tested.
6. Outcome assessor blinded	SATISFIED	No code breaks before end of trial. Treatment likely to be equally credible as The Back Book was the only difference in treatment intervention. Patients were unaware of different booklets.
7. Intention to treat analysis (ITT)	Not satisfied	ITT not documented and loss to follow up was more than 20% (sensitivity analysis carried out)
8. Compliance acceptable	SATISFIED	1 patient denied reading the booklet but high loss to follow up
9. Groups similar at baseline	SATISFIED	Statistical tests carried out for differences between baseline scores
10. Care provider blinded	SATISFIED	Booklets were distributed to patients in sealed envelopes
TOTAL	7/10	

Table 38. Methodological quality criteria for trial by Burton et al (1999)

Criteria	Jellema 2005	
1	SATISFIED	Randomised at the GP level according to random tables
2	N/A	No concealment was necessary. GPs selected 10 consecutive patients and treated according to pre-arranged randomisation
3	SATISFIED	Drop out acceptable and described. 8% in brief intervention group and 9% in usual care group.
4	Not Satisfied	Co-intervention described but not acceptable in the brief intervention group as 18% of patients were referred to a therapist even though GPs were explicitly asked not to refer. Referral rate was comparable between groups between 13 and 52 weeks.
5	SATISFIED	Patients were unaware of different strategies as pre randomisation design was used
6	Unclear	Not documented
7	SATISFIED	Intention to treat analysis included
8	SATISFIED	6 patients did not comply with brief intervention strategy
9	SATISFIED	GP and Patient data similar at baseline
10	Not satisfied	No evidence of clinical equipoise
Total	6/10	

Table 39. Methodological quality criteria for trial by Jellema et al. (2005)

Questions	Burton et al (1999)	Jellema et al. (2005) (2005)
Are the patients described in detail so that you can decide whether they are comparable to normal practice?	Yes	Yes
Are the interventions and treatment settings described well enough so that you can provide the same for similar patients?	Yes	Yes
Were all clinically relevant outcomes measured and reported?	Yes	Yes (fear avoidance only used as baseline)
Is the size of the effect clinically important?	Yes for fear avoidance and back pain beliefs NO for pain and disability	No for all outcomes
Are the likely treatment benefits worth the potential harm?	Yes	Yes

Table 40. Clinical relevance of included trials

DISCUSSION

The two trials that met the criteria for this review included information based on The Back Book. The Back Book was not designed to be used entirely in isolation yet only by excluding other treatments from a protocol is it possible to assess the true impact of the intervention. Both trials were of high methodological quality although loss to follow up was higher in the study by Burton et al (1999) (>20%).⁴³ The two trials included patients with acute and sub acute back pain with similar baseline disability scores (10-11 points on the RMDQ) but were heterogeneous in terms of the control intervention and it was therefore meaningless to pool results. Overall, there is limited evidence from the trial by Burton et al (1999)⁴³ that The Back Book results in long term reduction in fear avoidance and improved back pain beliefs compared with traditional back care advice. However, there is no evidence from either trial to suggest that bio-psychosocial education in a single consultation session results in reduction in pain, back disability, sick leave, and general health or recovery time in patients with acute and sub acute low back pain.

The trial by Jellema et al. (2005)²⁸³ included more focused psychological assessment and was the only trial to attempt to address the social aspects of the bio-psychosocial model. The additional psychological assessment was designed to strengthen the effect of the intervention by targeting factors that are thought to contribute to back pain recovery. Even with this additional focused assessment, no differences were seen between the brief intervention group and usual care in the primary outcomes (disability, perceived recovery rate and sick leave). The possible reasons for this finding are discussed by Jellema et al.(2005).²⁹³ The authors suggest

that the outcome may have been due to the suboptimal training of the GPs, insufficient intervention time (20 minutes) to change or influence patients' thoughts and beliefs about low back pain and possibly failure to assess the process adequately by using measures that were not sufficiently responsive and/or using inadequate duration of follow up. Another explanation for the non significant result could be due to the design of the trial. Patients with acute and sub acute low back pain are known to recover rapidly without intervention²⁹⁴ and brief intervention of only 20 minutes was unlikely to have a significantly greater effect than evidence based usual care. The usual care group received re-assurance, advice and analgesia based on the Dutch College of General Practitioners guidelines which has been shown to be effective for patients with acute low back pain.²⁹⁵

Studies excluded from the review

This review only included trials that assessed the effectiveness of back care education delivered in 1 or 2 sessions using a bio-psychosocial approach. It excluded six trials that used The Back Book in both arms of the study.^{263 265 278-282}

Two of these trials used The Back Book in isolation but compared it with other treatment in addition to The Back Book.^{263 278}

Four of the excluded trials that did not fit the inclusion criteria of this study failed to show any reduction in back pain or disability when compared with usual care or other types of education.^{148 260 266 272} Two trials have shown only small benefits in terms of patient consultation rates or satisfaction.^{260 271} It is not possible to conclude from this review whether the results would have been different if all back booklets were included. The recent review carried out recently by Henrotin et al (2006) did

not find any further evidence to change this conclusion. The small number of studies that fitted the criteria for this review suggests that either brief educational intervention are generally not considered as a treatment intervention per se, or that trials investigating the effectiveness of this treatment are not considered worthwhile because of the ethical problems or funding difficulties.

Controlled studies of bio-psychosocial intervention

A quasi-randomised French trial compared The Back Book with non-standardised verbal information in an inpatient rehabilitation setting for 142 patients with sub-acute and chronic pain. Both groups had additional physical therapy. Patients receiving The Back Book had significantly less disability at 3 months and were more satisfied with treatment but there was no difference between groups in fear avoidance beliefs.²⁹⁶ These results are in contrast with the study by Burton et al. (1999)⁴³ who showed significant improvements in fear avoidance beliefs in patients who were given The Back Book compared to those who were given a traditional booklet but no differences in disability between the groups.

An unpublished French trial by Coudeyre et al (2005) ²⁹² suggests that giving The Back Book to patients with acute low back pain reduces the number reporting persistent pain (10.5% vs 14.1%). Unfortunately it is not possible to make firm conclusions about the trial results as the methodology is not fully explained in the abstract and no further data was made available following correspondence with the author.

One other population based study that did not fit the criteria for this review was identified as important.²⁹⁷⁻²⁹⁹ The study was a quasi-experimental, non-randomised

controlled trial including a telephone survey of the general population and postal survey of general practitioners. The study was carried out in Victoria, Australia and an adjacent state was used as a control arm. The aim was to alter beliefs about back pain, influence medical management and reduce disability and cost of compensation. It included 4730 members of the general population and the intervention was based on the messages in The Back Book. Five hundred and fifty six GPs were questioned and followed up for 2 and 3 years. The intervention included a public health campaign carried out between 1997-1999. Television commercials, radio and printed advertisements, billboards, posters seminars, workplace visits, and publicity articles were included over a period of 1 year. Additionally, The Back Book was made widely available, with translations in 16 languages. Patients' Back Pain beliefs and GPs' beliefs were measured along with the number and duration of back pain and medical claims. Subjects were followed for 2 ½ years and then a further 3 years. This controlled study of an intense intervention resulting in significant sustained improvement in population beliefs and at the earlier follow up, reduced disability and workers compensation. The effect of the media campaign appeared to be sustained but dilution of observed effects were noted in the longer term follow up indicating that reminders and alternative strategies are necessary to maintain effects. Patients' beliefs about back pain management are known to influence the outcome of treatment.³⁰⁰ More recently research has demonstrated that it is not only the patients' beliefs but health care professionals' beliefs that are important.³⁰¹ Klaber Moffett et al (2000) surveyed members of the general population aged between 20 and 60 years, including a representative sub sample of 40% who had experienced

back pain in the previous year. Knowledge and perceptions about back pain, expectations and its best management were investigated. Misconceptions about back pain were found to be high particularly in those that had consulted a GP for their back pain.³⁰² This suggests that GPs' beliefs can influence patients' beliefs. In a cross-sectional study carried out in France (n=864) general practitioners' (GPs) fear avoidance beliefs were found to influence their adherence with guidelines negatively concerning physical and occupational activities. Many of the GPs believed that activity may be harmful for common low back pain and should be avoided.³⁰¹ Bishops et al (2005) carried out a cross-sectional study of 900 trained physiotherapists in the UK. The aim was to determine if physiotherapists could recognise patients at risk of developing chronic disability due to psychological factors. In addition they reported the type of advice given by physiotherapists to patients. The response rate to the survey was 57.7%. They found that most physiotherapists could recognise patients at high risk of chronicity but 34% of therapists reported that they would advise a patient with a high risk of chronic disability to stop work. The findings from these surveys are important and relevant to the outcome of this review because it is possible that the beliefs and perceptions about back pain, held by patients and health care providers, reduces the impact of brief bio-psychosocial educational intervention.

Reviews of brief educational intervention for back pain

Three reviews of brief educational intervention and individual patient intervention have been published recently which include trials up to 2004.

The European guidelines review did not specify interventions clearly, describe the search strategy in detail or identify clear inclusion and exclusion criteria.²¹ It included higher intensity intervention than the review described in this thesis. A variety of brief educational interventions were included ranging from cognitive behavioural programmes to one session of advice. Different methods of delivering the education were also included e.g. face to face education, internet education or telephone advice. The Oxman and Guyatt index was used for scoring the quality of the trials.⁹⁵ The guideline panel concluded that there is strong evidence that brief education interventions are as effective in reducing disability as routine physiotherapy or aerobic exercise. This conclusion was based on two heterogeneous trials^{278 303} (including the trial reported in this thesis) and therefore this recommendation should only apply to patients with minimal/moderate disability.

Engers et al (2006) reported a systematic review of individual patient education for low back pain including papers published prior to and including 2004. The individual patient education was defined as ‘any set of planned condition-specific educational activities in a one to one situation designed to improve patients’ health behaviours and/or health status’. A diversity of interventions was included from five minute oral advice to a multidisciplinary programme lasting up to three hours. Eighteen papers were included of which ten were of high quality. Strong evidence was found to support oral educational sessions lasting for 2.5 hours compared with no intervention in returning patients with sub-acute low back pain to work. Individual education was as effective as other intervention with regards to long term

pain and global assessment. However, comparisons of different types of education did not show significant differences.³⁰⁴ This review was in abstract form only and therefore difficult to assess in terms of quality. It is currently being updated prior to publication. (Engers 2006 Personnel communication).

The third review by Henrotin et al (2006)³⁰⁵ included 11 trials published before April 2004 and used the same methodology as the other reviews. Both randomised and controlled prospective studies were included. The objective was to determine which type of information was most effective compared with other interventions. The review was generally of high quality but had one major flaw which was the poorly defined inclusion criteria. The authors did not define the intensity or type of interventions clearly and although they did not identify studies including group intervention such as backschools in their review there was no criteria specified to exclude them. This suggests that there was some bias in the selection process. Evidence was conflicting but the authors concluded that information based on the bio-psychosocial model is the most efficient strategy. There was insufficient evidence to support information alone as an effective intervention in preventing LBP occurrence and recurrences.

Review limitations

This review is limited by the single reviewer who searched the literature and extracted the data. However the data was collected in a systematic fashion following the framework of the Cochrane Collaboration and the quality of the included trials was assessed by two reviewers. The small number of trials available for inclusion also limits the overall conclusions.

Conclusion

The evidence to support the effectiveness of brief bio-psychosocial intervention delivered in two sessions or less is weak although results of the unpublished French trial ²⁹² may change this conclusions. Evidence excluded from the review suggests that this approach may have more impact if it is used as part of a management strategy where the messages are reinforced with more intensive and expensive intervention. Recent high quality UK trials that have assessed physiotherapy management of back pain all report small treatment effects between interventions²⁶³
^{264 306 307} and therefore the use of brief advice as management strategy should not be ruled out.

Chapter 10

Discussion

SYNOPSIS

This chapter presents the closing discussion in four sections. The first section focuses on the internal and external validity of the trial. The second section discusses the trial results in context with relevant literature and back pain guidelines. The third section discusses the results of the systematic review of brief bio-psychosocial education. It focuses on the methodological limitations of systematic reviews in general and in relation to the review in this thesis. This section draws on and discusses methods of improving education advice. The final section discusses the clinical impact and implications of the trial for physiotherapists, patients and purchasers.

SECTION 1: DISCUSSION OF TRIAL RESULTS

Health service commissioners, clinicians and researchers were the driving force behind the conception of this trial. The pragmatic trial design was chosen to reflect current practice within the UK NHS. Pragmatic trials are more useful to clinicians than experimental designs because they assess treatment effectiveness in the real world in realistic conditions.³⁰⁸ This trial set out to find evidence for routine physiotherapy treatment delivered in a UK NHS setting. The hypothesis (*Patients with sub-acute and chronic low back pain who attend routine physiotherapy treatment will report significantly less disability, pain and improved general health over one year, compared with patients who attend a single session of self-*

management advice given by a physiotherapist) was rejected and null hypothesis accepted. While some would view this as pessimistic for the physiotherapy profession it is important to recognise that research whether positive or negative in outcome generally contributes to knowledge and can indirectly improve the overall management of patients as long as the methodology is valid and satisfies scientific scrutiny.

Accrual rate and trial difficulties

The trial took longer than anticipated to complete and a number of factors, that were difficult to predict, affected the recruitment rate. Due to the long recruitment phase it was important to maintain motivation of staff and set backs were dealt with as they arose at regular collaborator's meetings.

One centre dropped out in the very early stages of recruitment because of staffing difficulties. At the Horton General Hospital it was difficult to recruit a trial research therapists and that delayed recruitment at that centre for eight months.

A fast staff turnover rate meant that motivation of participants was difficult and new members of staff needed to be constantly updated. While this was a disadvantage in terms of recruitment it did mean that the patients were treated by a broader number of therapists making the trial results more generalisable.

One centre was seriously affected half way through the recruitment phase by another larger trial (UK BEAM) setting up and recruiting similar patients in the same area directly from the GP practice before referral to physiotherapy. This led to complete failure of recruitment in the Wallingford Community hospital.

The slow recruitment, caused by long waiting times and patient refusals, raised the question of whether it was ethical to continue or abandon the trial with a small number recruited. Small trials with inadequate numbers carry a considerable risk of failing to demonstrate a treatment difference when one is really present (type 2 error).¹⁶¹ Peto et al (1976)³⁰⁹ points out that publication bias is accentuated because many clinical trials, including medical, surgical and conservative therapy, are grossly undersized. Abandoning the trial with small numbers would have resulted in a waste of researchers, patients and clinicians time as well as funding. Therefore further funds were sought and awarded to finish the trial with adequate numbers.

Internal validity of the trial

The trial was based on an a priori sample size estimate, essential to minimising the risk of a false negative (or positive) result. Loss to follow up at the two and six month follow up assessments was within bounds of acceptability. The sample size was based on a standard deviation of 8% points on the Oswestry Disability Index but the actual standard deviation was 11% points. If this standard deviation was used in the power calculations it resulted in a power of 86% to detect a 4% difference between the groups. The follow up rate of 70% at 12 months meant that the study had slightly reduced power but the mean difference between groups in the ODI scores was only -1.04 (95% confidence interval -3.7 to 1.59) so it was very unlikely that clinically significant differences would have been found.

Great care was taken during assessment and data collection in this study to ensure concealment of treatment allocation from investigators. Although not formally assessed there was no evidence to suggest that the trial investigators became aware

of the allocation until the analysis was complete. Blinding of patients, investigators and care providers are important to the internal validity of trials¹⁶⁵ but it is often impossible to blind clinicians and patients in trials of physiotherapy intervention. The Cochrane Collaboration Back Review group for spinal disorders updated the methodological scoring system in 2003 and blinding of care providers was recognised as not being applicable to trials of exercise intervention.⁹⁰ Colle et al (2002)³¹⁰ point out that certain scales are more suitable for particular trials and this applies in particular to trials of exercise or surgical intervention where it is impossible to blind patients to intervention.

A researcher, unaware of treatment allocation, carried out the baseline assessment. The coded follow up questionnaires, posted to the data administrator, made it unlikely that bias affected the results. The baseline characteristics of the patients were similar supporting the conclusion that the randomisation procedure was successful. Coded data analysis made investigator bias impossible and therefore this aspect of internal validity was not threatened.

Protocol violation

Protocol violations, where details of the trial plan are not followed precisely by all patients, are unwelcome but not uncommon in randomised controlled trials.^{263 306 311}

The importance of violation depends on how they affect the inference from the trial.

In this trial the potential source of bias was the 18% of patients in the advice only group that went on to have additional treatment. However, the per protocol analysis yielded similar results to the intention to treat analysis and consequently it is

unlikely that any bias that may have been caused by this violation, effected the results.

There is a small amount of research investigating patients experience of trials³¹²⁻³¹⁴ but little information on the experience of clinicians involvement in trials, particularly in the physiotherapy profession. Clinician compliance with trial protocol is rarely reported adequately in randomised controlled trials and while it is common for patients to seek additional treatment, little is reported or known about clinician adherence with trial protocols.³¹⁵ The reasons for non-compliance are complex and it was impossible to control for clinical decisions during the trial due to patients' fluctuating symptoms and physiotherapists' beliefs about treatment effectiveness. It was possible that the physiotherapists' beliefs about treatment effectiveness may have influenced the patients in this study but this potential bias was difficult to control, other than through open discussion prior to the trial implementation that took place during the development phase at collaborators meetings. Formal assessment of the physiotherapists' views and clinical equipoise (where two treatments are considered to be equal), prior to implementation may have been useful in detecting those who were likely to cause any potential bias.

Non response bias

The main threat to the internal validity was the loss to follow up at 12 months and missing data, which in spite of postal reminders, telephone calls, and patient diaries to help recall, was high at 30%. Missing data can generate bias and reduce the internal and external validity of a study. However, in this study there were only minor differences at baseline between responders and non-responders and no

differences in primary outcome scores (ODI) between responders and non responders. In addition, there were no significant differences between those randomised to physiotherapy or advice in the responders and non responders groups suggesting that the data was missing at random.²⁰⁷

The reasons for non response are difficult to predict and potential confounding factors such as smoking may have affected the outcome of the study because smoking is associated with the incidence and prevalence of back pain.³¹⁶ It is possible that the smokers who did not respond were less likely to improve compared with the non smoking responders.

There may also have been differences between groups in the reasons why patients did not respond. It is possible that those in the physiotherapy group did not respond because they had improved at two months yet those in the advice group did not respond because they had deteriorated. If this was the case then loss of this data would have underestimated the effect of the additional physiotherapy treatment.

Loss to follow up is a common problem in trials where data is collected over longer periods of time^{179 265 317 318 161} and other reasons such as psychological problems, health related problems, travelling costs or a poor relationship with the clinic^{319 320} may have affected the response rate. The follow up rate in this study may have been improved by more intensive attempts to contact the patients' general practitioner or by using national registers.

Replacement of missing data aims to reduce bias but can also lead to underestimates or over estimates of effects. Various methods can be used that preserve the sample size but make assumptions about the missing data. These include replacing the

missing data with the group mean, multiple imputation that maintains the estimate of both the mean and the standard deviation, and the last observation carried forward method.³¹⁷ However none of the methods of analysis used in this study (intention to treat using only the available data, intention to treat using the last value carried forward method and the per protocol analysis including data from those patients who complied with the treatment protocol) produced significant differences between groups. The last value carried forward method was reported in this thesis as it gave the most conservative estimate of the effects. The disadvantage of using the last value carried forward method was that the greatest loss to follow up was between 2 and 6 months and at 2 months the patients in the physiotherapy group had a slight advantage over the advice group. Any advantage at that point would then be carried forward to the 12-month follow up resulting in bias in favour of the physiotherapy group. Even with this potential bias, there were no significant differences at the 12-month follow up. As estimates of the treatment effect were very similar using raw and imputed data in the statistical analysis it was unlikely that the internal validity of the study was affected significantly by non response bias.

Responsiveness analysis

The effect sizes of both interventions were small but the responsiveness analysis confirmed that the primary outcome was capable of detecting estimated change when the data was categorised into those that improved, deteriorated or remained the same. As discussed in chapter eight, the validity of measures varies depending on the population, type and severity of back pain and in this group of patients baseline disability levels were generally low. The responsiveness analysis supports the

internal validity of the outcome measures used in the trial in which the patients had low levels of baseline disability. However, ideally each measure should be tested in the context in which they are used.

External validity of the trial

One of the strengths of the trial was the method of recruitment that reflected routine practice in the NHS at the time. The study was based primarily in secondary care but referrals came from general practitioners (89%), orthopaedic consultants (6%) or triage and sport clinics (5%) to local physiotherapy departments as routine referrals. The majority of patients were referred from general practitioners and it was therefore unlikely that the population would have been different if the trial had been based in primary care. In addition, all patients referred for physiotherapy were invited to take part in the trial regardless of the level of disability. This may have resulted in a lower level of reported disability compared with other trials^{306 307 321 322} but it did reflect routine referrals and made the trial more generalisable.

When trials are run over long periods of time it is possible that service provision and interventions change, reducing the trial's applicability. In the lead centre a triage clinic was established during the trial recruitment phase but it did not affect intervention.

The interventions included commonly delivered treatments similar to that reported in UK surveys and there was no evidence to suggest that practice changed dramatically during the trial recruitment phase.^{62 64} It was therefore unlikely that the external validity of the trial was affected by change in practice.

Patients were recruited in southern England and socio-demographic factors have been shown to affect outcome in different parts of the UK. It was possible that the trial outcome would have been different if carried out in a different part of the UK and this threat to external validity cannot be ruled out.²⁶⁴

Selection bias

An objective of the trial was to ensure that the patients recruited represented a target population to whom the trial's findings may be applied.¹⁶¹ The audit of new patients with back pain in Oxfordshire carried out in 1994-1995 suggested that approximately 3000 patients were referred for physiotherapy per year yet only 508 patients were identified and 286 included. A proportion of the 3000 patients would have had other types of back pain, acute low back pain or more serious spinal pathology and some of the patients with chronic low back pain would have been referred directly to pain management or functional restoration programmes. In addition, approximately 6%-10% of patients do not attend initial physiotherapy appointments in Oxfordshire. Unfortunately, no structured information was available in Oxfordshire or Reading on the characteristics of all patients attending outpatient physiotherapy and, for ethical reasons, no data were collected from patients who did not agree to participate in the trial. It was therefore impossible to assess differences between those that participated in the trial and those that did not. Patients that were identified as potentially eligible were not obliged to give a reason for refusal. It was possible that patients with higher disability levels may have found the advice only arm of the trial unacceptable. Twenty one out of 222 (9.5%) refusals reported this as a reason for not participating in the trial but only 43 patients offered a reason for non

participation. Hence it is possible that as many as 50% of patients may have refused for this reason.

The case mix of patients with low back pain and leg symptoms described in Table 13 suggests that the population included a heterogeneous group of patients with mild to moderate disability. This was probably because a minimum threshold of disability was not specified in the exclusion criteria. Selection bias can be introduced by including a threshold of severity in trial entry criteria but this was not the case in this study.

Patients who have to wait for long periods of time for treatment, are less likely to participate in trials particularly if they perceive one arm of the trial to be less attractive.³¹⁵ The problems of staff shortages and long waiting times in some centres may have resulted in a bias in selection of patients resulting in only those with minor disability participating. However, the SF-36 scores suggest that the population was similar to patients with back pain consulting physiotherapists in the general population.³²³

Observation of the recruitment rate (Table 12) at each trial centre and the baseline data (Table 13) demonstrates that the randomisation process was successful but only a small number of patients were recruited from the lead centre. This centre was a specialist unit where most referrals were from consultants dealing with complex chronic patients who referred patients for more intensive physiotherapy.⁵⁹

Variation in recruitment between physiotherapy departments reflects the size of each centre and in some cases organisational difficulties.

It was impossible to assess the extent to which the patients included in the trial were typical of all referrals without better routinely collected data on all referrals to the physiotherapy departments. Taking into account the potential number of patients that were ineligible or not identified it is possible that the selected patients did not reflect the full spectrum of non-specific low back pain in the community. However, the results do represent a substantial sub group of patients with minimal/moderate back pain disability that are routinely referred for physiotherapy intervention and are also seen in the primary care setting.

Treatment preference

Patients' expectations and pre-conceived ideas about treatment can influence outcome. Some patients may be disappointed if they do not receive their preferred treatment or conversely have a better outcome, irrespective of treatment efficacy, if they do.^{324 325} In this trial, treatment preference was not assessed but other physiotherapy trials have found that outcome was not influenced by patients' preference.^{326 327}

Equipoise of patients and physiotherapists

Over the last 10 years, there has been an increasing awareness of issues associated with the quality of trials including questions about precision, bias and validity.³²⁸

Decisions that influence the behavioural dynamics of participant's (of both recruiting clinicians and the eligible patient population) may affect the internal and external validity of the trial.³²⁹

In this study the trial team was aware of the potential bias caused by patient and clinician beliefs regarding treatment equality. The requirement of an open discussion of clinical equipoise with patients is an obstacle for recruiting clinicians.^{176 330-332} Most of the clinicians in the Oxfordshire region had no experience of participation in clinical research and training sessions were organised to provide information and discuss barriers to successful implementation. During the training sessions some clinicians raised concerns about offering a single treatment session and questioned the equality of the interventions. The ethics of clinical research requires equipoise where two treatments are considered to be equal, however, true equipoise is rarely present and most randomised controlled trials present challenging ethical dilemmas.³³³ Freedman¹⁷⁶ presents an argument for clinical (collective) equipoise based on controversy surrounding the effectiveness of treatment amongst the clinical community rather than on the beliefs of individual clinician over the preferred treatment. Edwards et al. (1998) cite 19 articles that regard the existence of collective equipoise as sufficient justification for a trial, that is, a trial is considered to be ethical if experts in general, rather than the particular clinician are in equipoise.³¹⁴ Unlike trials involving high risk (possible death) or large expected benefits, physiotherapy trials rarely pose a problem.

Following discussion of treatment equality and clinical equipoise it was clear that some physiotherapists were not comfortable delivering the trial protocol for perceived ethical reasons, lack of experience or lack of confidence in providing advice only as an intervention. Clinicians were not encouraged to be involved if they held strong beliefs that would affect the internal validity of the trial. In

retrospect, it would have been interesting and informative to collect qualitative data alongside the trial investigating the views and beliefs of the participating clinicians. Innovative ideas are emerging in recent trials to assess potential bias caused by trial participants. In a high quality trial of physiotherapy intervention for neck and back pain patients, clinician adherence to the trial protocol was assessed using videotape consultations between the patients and therapist.³²⁶ This was a novel idea that helped to evaluate the therapist's skills in switching from one approach to another but there was no guarantee that they would behave in the same way when not under scrutiny.

SECTION 2: COMPARISON WITH RELATED RESEARCH

Over the last two decades, publication of many trials and reviews of treatment for back pain have led to the development of international guidelines. Guideline recommendations vary between countries, but all suggest early activity and reassurance. The most up to date and comprehensive are the European guidelines commissioned by the European Co-operation in the field of Scientific and Technical Research (C.O.S.T) that were compiled by a team of international back pain experts.^{21 251} The guidelines based recommendations on evidence but also consensus. The Royal College of General practitioners guidelines published in 1996, are superseded by the NHS (2005) Prodigy guidelines.³³⁴ These guidelines are relevant to this thesis because the trial results have contributed to them.

The patients in this trial had mild to moderate levels of disability as measured on disease specific outcomes. Some would argue that such low levels of disability do not warrant expensive NHS physiotherapy treatment. However, the SF-36 scores

suggested significant disability when compared with the normal population particularly in physical functioning, role physical and pain items of the questionnaire. Scores were similar to those of patients with back pain consulting physiotherapists in the general population and worse than those of non-consulting back pain sufferers.³²³ Clearly the patients felt that they wanted or needed treatment or they would not have bothered to attend for their appointment and the GPs referred the patients without prior knowledge of the trial so they must have agreed that the patients required treatment.

A study by Moffett et al. (1999)³²⁷ is the only other trial to report similar baseline disability scores as those reported in this thesis. The trial was of high quality with a low drop out rate at 12 months (9%). One hundred and eighty seven patients with sub-acute pain were recruited and baseline Roland and Morris Disability questionnaire (RMDQ) scores were low (mean 5-6 points). Larger health gains were reported in patients who attended a physical fitness programme including a cognitive behavioural approach, compared with the control group that had routine primary care management. The difference between the groups at 12 months was small but statistically significant (mean difference in RMDQ 1.42, 95% confidence intervals 0.29 to 2.56: $p < 0.02$) in favour of the physical fitness group but patients in that group also reported only 378 days off work compared with 607 in the control group. The compliance with the physical fitness programme was good (73% attendance of six to eight sessions). The results suggest that for patients with minimal disability, exercise programmes, with good compliance that are graded to ensure improvements

in cardio-vascular and/or muscular strength, may be more beneficial than the routine physiotherapy intervention described in this thesis and more commonly practiced in the UK. ⁶²

Trials of spinal joint mobilisation and manipulation

Comparisons with the trial in this thesis can be made with the large MRC funded UK back pain, exercise and manipulation trial (UK BEAM). The UK BEAM trial compared the effect of adding manipulative therapy and physical exercise classes (Back to Fitness programme) ⁵³ to General Practitioner advice supplemented with The Back Book. One thousand, three hundred and thirty four patients with sub-acute and chronic low back pain were recruited from 181 centres across the UK. The RMDQ was used as the primary outcome and patients were excluded with scores of less than four out of 24 on the scale. Small to moderate benefits were achieved by adding manipulation and exercise to advice 3 and 12 months after randomisation. Overall, the manipulative therapy group benefited more in terms of reduced disability but the differences were small (difference between exercise and GP care at three months; 1.4 (95% confidence interval 0.6 to 2. For manipulation the additional improvement was 1.6 (95% confidence interval 0.8 to 2.3) at three months and 1.0 (95% confidence interval 0.2 to 1.8) at 12 months. For manipulation followed by exercise the additional improvement was 1.9 (95% confidence interval 1.2 to 2.6) at three months and 1.3 (95% confidence interval 0.5 to 2.1) at 12 months. The UK BEAM trial included a similar patient population to those described in this thesis but with higher baseline disability scores. Small differences were found between the advice group and therapy groups but the differences were not necessarily clinically

important to patients. The advice group was similar to the advice group in this thesis, differing only in that GPs gave the advice in the UK BEAM trial. It would be incorrect to assume from these two trials that manipulation and physical fitness exercise is more effective than routine physiotherapy intervention. However, in a smaller (n=290) UK trial with similar baseline scores to the UK BEAM trial, Carr et al (2005)²⁶⁴ compared a 'back to fitness' programme⁵³ with individual routine physiotherapy and found no significant differences between groups in the primary outcome (RMDQ) at the 12 month follow up. These two trials suggest that the effects of routine physiotherapy, manipulative therapy and physical fitness may be similar in patients with moderate back pain disability and slightly more beneficial than a one off session of advice but this does not apply to patients with less severe disability.

The second most common treatment reported in the trials was joint mobilisation but use of high velocity thrust manipulation was uncommon, reflecting routine physiotherapy practice.^{62 73} The UK BEAM trial suggests that manipulative therapy is more effective than evidence based advice given by a general practitioner but it is unclear from the paper how much high velocity thrust manipulation patients received. A minimum basic treatment requirement of one high velocity thrust technique was included in the protocol and 92% of the 686 patients received this. Consequently, the treatment effects may have been due to other manual therapy including spinal mobilisation techniques or even exercise rather than the manipulative therapy.

European guidelines reviewed 18 trials of manipulative therapy for chronic low back pain and seven systematic reviews. They concluded that there is moderate evidence that manipulative therapy is superior to sham manipulative therapy or usual GP care alone. They also found moderate evidence that spinal manipulation is no less and no more effective than back schools or other types of physiotherapy/exercise therapy for chronic low back. There is no clear evidence to support high velocity manipulative therapy over and above spinal mobilisation techniques particularly when carried out by physiotherapists. European guidelines recommend a short course of spinal manipulation/mobilisation for acute and chronic low back pain when patients fail to recover spontaneously^{21 251} and the study in this thesis suggests that for those with simple, less severe low back pain one session of advice should be the first line of management.

Exercise for non-specific low back pain

Exercise was the most popular intervention in the study in this thesis accounting for 94% of treatments. This was in line with current physiotherapy practice in the UK.⁶² In 1996, when the trial was implemented there was no evidence for any specific exercise. Since then there have been a number of studies assessing specific types of exercise for back pain,^{116 246 263 303 306 318 321 326 327 335 336} in particular spine stabilization,^{321 337} McKenzie exercises³²⁶ and physical fitness programmes.^{327 338}

Review of exercise for acute and chronic low back pain

Hayden et al (2005)²⁴⁶ published a meta-analysis of exercise therapy for non-specific back pain and it is the most comprehensive review to date. The high quality review

included a standard protocol for study selection and data abstraction.⁹⁰ Sixty one randomised controlled trials including 6390 patients were reviewed including 11 acute, 6 sub-acute, 43 chronic low back pain and one that was unclear. Exercise therapy was found to be effective in chronic low back pain relative to comparisons but patients with less severe disability were not included. The evidence for sub-acute low back pain was less conclusive. No evidence was found that suggests exercise therapy was any more effective than no treatment or any other type of conservative treatment.

In a secondary analysis of the chronic low back pain data Hayden et al (2005) concluded that exercise therapy consisting of individually designed programmes, including stretching and strengthening demonstrated the largest improvements over comparisons.³³⁹ In addition, the more intensive exercise programmes were more effective than programmes that were less than 20 hours duration.³³⁹ From a NHS clinical perspective it is unrealistic to suggest more than 20 hours of treatment for patients with simple chronic low back pain.

Trial of physiotherapy compared with physical fitness exercise and advice

When the trial in this thesis was published it was compared with a trial carried out in Norway³⁴⁰ although there were differences between the trials in advice given, severity of back pain and intensity of treatment. Torstensen (1998)³¹⁸ randomised 280 patients with chronic LBP to either conventional (routine) physiotherapy (including heat, cold, electrotherapy traction, massage, exercise), a progressive

graded exercise programme or advice to exercise. The intensity of treatment was high including 36 hours in both treatment groups. Patients in the advice group were advised to walk for 1 hour, 3 times a week. There were no differences between the conventional therapy and exercise group but both were superior to the advice only group. This was not surprising considering the intensity of the treatment. All patients were sick listed between 8 and 52 weeks and baseline disability levels were much higher than reported in the trial in this thesis (approximately 50% ODI scores). Patients were still severely disabled following treatment (ODI 45%). The comparison between these trials highlights the problems associated with interpreting heterogeneous studies using the same classification of chronic low back pain but not taking into account severity.

Trials of McKenzie exercise

The McKenzie method of assessment and treatment was a popular treatment choice in this trial although there is limited evidence to support its effectiveness.³⁴¹ A study carried out in the USA on 321 patients with sub-acute low back pain compared McKenzie method of physical therapy, chiropractic manipulation and an educational booklet. This was a high quality trial including an intention to treat analysis with a follow up rate of 86-96%. The patient compliance rate with treatment was the same as the trial in this thesis with 18% of patients in the booklet group seeking additional treatment. There were no differences between the manipulation and the McKenzie groups and patients receiving these treatments had only marginally better outcomes than those receiving the information booklet at 4, 12, 52 and 104 weeks after treatment.²⁷⁵

A high quality UK trial recruited 649 patients with neck or back pain and compared McKenzie exercises and brief physiotherapy pain management with or without back advice. They found no statistically significant difference in outcomes between groups although patients in the McKenzie group were more satisfied with treatment.

³²⁶ The popularity of McKenzie techniques is most likely due to heavy marketing of post-graduate physiotherapy courses. The McKenzie (1981) ⁸¹ technique requires patient commitment and it has the advantage over other more passive treatments such as manual therapy, of encouraging activity rather than rest.

Trials of spine stabilisation exercises

Spine stabilisation exercises were the most popular choice of exercise in this trial but evidence for their effectiveness is lacking. A low quality review based on small randomised and non-randomised trials was reported by Akuthata et al (2004).⁴⁹ The authors reported little evidence to support the efficacy of the spine stabilisation exercises over and above other therapies. A UK trial published latterly compared spine stabilisation exercises with manual therapy and a back school and reported a trend in favour of spine stabilisation exercises after one year.³³⁷ This was a low quality trial of poor methodology with no intention to treat analysis and consequently the results are contentious.³⁴² Another small trial of higher quality, but with poor follow up, reported no additional benefits of adding spine stabilisation exercise to routine physiotherapy.³²¹ Further research is necessary to demonstrate the clinical effectiveness of this exercise approach.

Intensity of treatment

Trial patients received a median of five sessions in the physiotherapy group and one session in the advice group. In terms of treatment duration, this amounted to, on average, approximately one hour in the advice group and up to three hours in the physiotherapy group. It may have been unrealistic, with this limited amount of treatment, to expect differences between the groups particularly at the 12 month follow up but intensity was based on clinical consensus and audit prior to trial implementation. In a survey of physiotherapy practice in the UK 53% of patients were treated between 4-6 times confirming that this intensity of treatment is typical of UK NHS practice.⁶² The meta-analysis by Hayden et al (2005) and a review of multi-disciplinary rehabilitation by Guzman et al (2001)^{343 344} both concluded that if exercise is to be effective for chronic low back pain it should be more intensive (>20 hours in total). However, for patients with minimal disability this would not be a practical approach.

Multi-disciplinary treatment for back pain

There is moderate to strong evidence that multi-disciplinary rehabilitation including general exercise programmes of muscle strengthening, flexibility training and cardiovascular endurance along with a cognitive-behavioural approach improves function, reduces pain and work loss in patients with chronic low back pain compared with usual care or non-multidisciplinary treatment.²¹

This type of treatment is labour intensive, not routinely available in the UK NHS and although recommended in the European guidelines for chronic pain,²⁶³ is

unlikely to be implemented rapidly due to the cost of establishing the service and lack of suitably trained therapists.

Compliance with exercise programmes

Compliance needs to be high for exercise interventions to be effective and no information was collected on exercise compliance in this study. There is a lack of trial data reporting exercise compliance probably because, if it is unsupervised and carried out at home, it is difficult to record accurately. The multi-centre UK BEAM trial²⁶³ demonstrated very poor group exercise compliance with only 63% of patients receiving basic minimum treatment (an assessment and 1 out of 8, 60 minute sessions). This was similar to a trial carried out in Northern England that reported low attendance rates (approximately 50% attending 5 or more sessions and 17% not attending at any).²⁶⁴ A single centre trial using a similar physical fitness programme reported a compliance rate of 86% total attendance.¹⁴⁴ The difference in compliance may reflect the difficulties involved in running multi-centre large trials compared with simple small single centre trials where it is easier to motivate trial participants. Alternatively, it may be due to regional differences or differences in socio-economic status.²⁶⁴ Patients who are highly motivated are more likely to benefit from exercise regimes and this should be taken into account and discussed with patients prior to treatment.³⁴⁵

SECTION 3: BRIEF BIO-PSYCHOSOCIAL EDUCATION

While there is strong evidence to support education as part of an intensive multi-disciplinary programme²¹ the efficacy of brief bio-psychosocial intervention is less

conclusive and the review in this thesis demonstrated that it is a weak intervention if used in isolation.

A major problem in the search for bio-psychosocial education advice was the terminology and lack of clearly defined intervention. Many researchers use the term bio-psychosocial to describe education intervention but it is not clear from most of the literature if education with any psychosocial input is actually incorporated in the advice. A definition was used to describe the bio-psychosocial intervention for this review but even so it was difficult to select studies because of poor reporting and lack of clarity. In addition the social aspects of the model are particularly difficult to define and in reality most interventions, including the trial intervention, do not actually deal with the social aspects of patients lives in any detail and this is evident from the lack of any clear information in the literature. There are additional limitations to this review that are discussed below but are common to all reviews.

Methodological problems of systematic reviews

Standards for systematic reviews (QUORUM) have helped to improve quality of reporting but there are numerous ways in which bias can be introduced. The selection criteria for any review is usually defined by the question asked in the review but it is open to bias by the investigators who are generally familiar with the literature and consequently can be influenced by their own prior knowledge. In addition citation bias (not using a wide source of search engines), language bias (restricting searching in English), biased outcome reporting (trials only reporting the most favourable outcomes), publication bias (trend towards reporting of positive

rather than negative trials) and bias caused by the poor quality of the trials included in the review can all contribute to erroneous conclusions.⁸³

Methodological problems in systematic reviews are not limited to reviews of back pain. In a study of 965 systematic reviews including paper based journals and Cochrane reviews, more than 50% were found to be methodologically flawed, particularly in the interpretation of quality assessment.³⁴⁶ Bias can occur when intervention criteria are not clearly defined or authors misinterpret descriptions of interventions. This was evident in a recent review of multidisciplinary programmes for back pain where a trial was included that did not fit the criteria for the review yet was given a high quality rating and used in the interpretation of the results.³⁴⁷ This type of error can lead to spurious conclusions particularly when small numbers of high quality trials are included in the review.

When designing a protocol for a systematic review of low back pain researchers need to choose between broad inclusion criteria that combines studies that are too heterogeneous to make firm conclusions or a stricter criteria that defines the type of intervention clearly but results in incomplete analysis of potentially relevant studies. Strict criteria were chosen for the review in this thesis because the main objective of was to investigate the effectiveness of the brief bio-psychosocial education alone. It is logical to compare only the treatment of interest without any other co-intervention in order to assess effectiveness but it is rare that any back pain intervention is used in isolation. Whilst it was clear from the review that brief bio-psychosocial education

intervention is not widely researched, the question was important because this type of intervention is recommended in the European guidelines.

Back pain guidelines for brief educational intervention

The trial in this thesis is included in the European guidelines for chronic low back pain in a section reviewing brief educational intervention.²¹ Since the publication of the European guidelines, two trials of high methodological quality have assessed brief bio-psychosocial intervention in the UK. Hay et al (2005) randomised patients with acute and sub-acute pain to a brief pain management programme (median number of sessions 3) or manual therapy (median number of sessions 4) and found no difference between groups in clinical outcome at the 3 and 12 months follow up.³¹¹ Both groups had relatively high levels of disability at baseline (mean RMDQ; 13.8 and 13.3) probably because 75% of patients were still in the acute phase. In a similar study Klaber Moffett et al (2006) compared a brief pain management programme (median 3 sessions) with the McKenzie approach (median 4 sessions) for patients with chronic neck or back pain.³²⁶ In addition, this trial further randomised patients to receive 'The Back Book' or not. There were no statistically significant differences between the groups at the 6 week and 12 month follow up but when treatment was supplemented with 'The Back Book' patients reported slightly more reduction in activity avoidance. Change in disability scores were much smaller than those reported by Hay et al. (2005) (approximate mean RMDQ change from baseline to 12 months was 4 compared with 9) which may be due to differences expected between patients with acute and chronic pain. Interestingly, the trial by Jellema et al (2005) 283 and Hay et al.(2005)311 are comparable because they both

include acute or sub-acute patients who, some would argue, are likely to improve regardless of treatment. Hay et al (2005) did not include a usual care group or no treatment group for practical, ethical and methodological reasons.³⁰⁷ Without a control group it is impossible to conclude that brief bio-psychosocial pain management or manual therapy are any more beneficial than usual NHS GP care for acute or sub-acute patients. The results of the trial by Jellema et al (2005) ²⁸³ suggests that this is an area of research that should be investigated further. The benefits of using bio-psychosocial education in a brief face to face contact of two sessions or less are likely to be very small. This type of brief bio-psychosocial education intervention is a relatively new approach to the management of back pain and it may be possible to improve outcomes by focusing on changing back pain beliefs of health care professionals as well as patients. In reality both the psychological and social aspects of the model are difficult to address in one or two sessions particularly without specific training.

Education and barriers to implementing evidence based practice

The UK NHS agenda has promoted patient advocacy and empowerment since the 1980's and the provision of good quality, evidence based, educational information developed with the involvement of patients and public, has been an important part of the process.^{348 349} The Back Book,¹² although developed in line with Royal College of General practitioners guidelines, did not directly involve patients in the development.³⁵⁰ In a qualitative study, McIntosh et al (2003) found that some patients thought the tone of the booklet was patronising and that labelling low back pain sufferers as 'copers' or 'avoiders' categorised patients unfairly.³⁵⁰ It is

impossible to know if this affected the outcome of the trial but it highlights the importance of not only ensuring that patient information material is evidence based but does not patronise or blame the potential reader. In a UK survey of subjects with and without back pain, assessment of perception about 'The Back Book' revealed that understanding and knowledge of back pain differed depending on an individual's previous experience. Those who had experienced back pain in the past were less likely to believe in information 'The Back Book' provided³⁰² highlighting the importance of considering symptom duration in treatment intervention.

Most of the recommended treatments for back pain involve education^{11 252} yet physiotherapy training focuses on physical interventions and assessment of pain,⁶² and not on teaching educational methods particularly in relation to communication skills and behavioural change that are fundamental for successful intervention. The relationship between knowledge, attitude and behaviour are positive but small and attitudes and behaviour are not closely related.³⁵¹ This suggests that the idea that providing information will change attitudes and stop patients behaving in an unhealthy way is flawed. It is not surprising that distributing educational information like 'the Back Book,' without any consideration for the process of change that is necessary to maximise potential benefit, results in very small effects.

A behavioural model for understanding adherence with education advice is described by Linton (2005) (See Figure 16).¹⁵⁵ On the left hand side are factors relating to whether the behaviour will be initiated and on the right hand side are factors that influence long-term adherence. This model illustrates that for patients with back pain to initiate change in health behaviour advocated in 'The Back Book',

they need to believe that their current behaviour may threaten their back pain state, that changing their behaviour will reduce the threat and that the pros of engaging in a more active approach are larger than the cons.¹⁵⁵

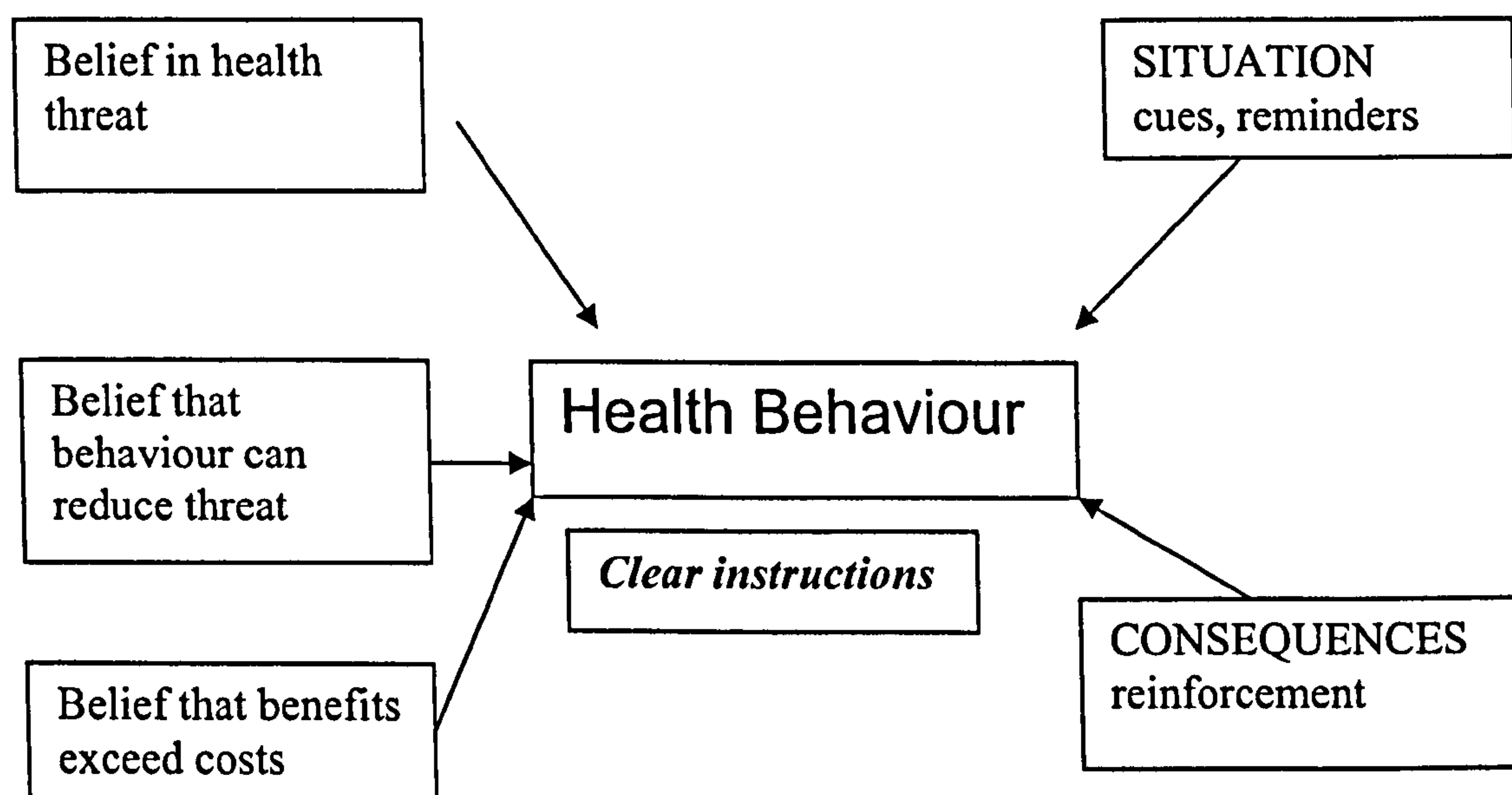


Figure 17. A health beliefs model (Linton 2005)

Prochaska and DiClemente (1982)³⁵¹ postulate that there are five steps to lasting behavioural change;

1. Pre-contemplation (no change is considered to be necessary),
2. Contemplation (a change is deliberated)
3. Preparation (the change is planned)
4. Action (initiation by engaging in the health behaviour)
5. Maintenance (sustaining the change over time).

In a one off session of advice, it is unlikely that the physiotherapists would have been able to focus on all these stages of behavioural change but it would be possible to focus on one aspect of the model and help the patients move through the cycle. In this study clinicians were not given extra training to deliver the education advice. In retrospect, if the physiotherapists had received additional training, prior to trial implementation, to help them deliver the messages in 'the Back Book', the benefits may have been greater but then the trial would not have tested routine intervention. In addition, any benefits of training would have been seen in both groups and therefore the results of the trial were unlikely to change.

Physiotherapists need to understand the complexities that are involved in the development and course of back pain including issues such as fear avoidance, patients' expectations, attitudes and beliefs to maximise any potential benefits of treatment.

Publication of back pain guidelines do not automatically result in clinicians following recommendations because barriers to change remain across the NHS.⁷⁶
³⁵²⁻³⁵⁴ Historical practices are notoriously difficult to change in the physiotherapy profession³⁵⁴ and evaluation of physiotherapists' beliefs is as important as focusing on patients' beliefs. Bishop and Foster (2005)⁷⁶ suggest that some physiotherapists, whilst understanding the risk associated with developing chronic back, do not use recommended advice that may help prevent it and this hurdle needs to be overcome within the profession in order to maximise change. It takes time to change the management of health care services but there is evidence from The Netherlands that

physical therapy services have changed with a decline in the number of treatment sessions and increase in the use of evidence-based interventions.⁷⁷

SECTION 4: CLINICAL AND COST IMPLICATIONS OF THE TRIAL

Comparison of costs

No significant differences in overall cost per patient were found between the groups in the trial due to the differences in intervention and patient costs, favouring the advice group, being partly offset by slightly lower other NHS costs. The number of additional physiotherapy sessions received by the advice only group was an important cost driver in these analyses and sensitivity analysis confirmed that had these patients received only their allocated treatment, the difference in total health care cost between the groups would have been significant. These additional sessions may have affected the outcomes of those in the advice group but the per-protocol analysis of the outcome data was similar to the intention to treat analysis.

The publication of the cost utility analysis of this trial allows comparisons between the cost effectiveness of physiotherapy and other NHS treatments.³⁵⁵ The estimated incremental cost effectiveness ratio of £3,010 per quality adjusted life-years (QALYS) lies within acceptable values of willingness to pay.³⁵⁶ However, the cost effectiveness acceptability curve suggests that because of the non-significant difference in effects, this type of routine physiotherapy compared with advice only will never have a very high probability of being cost-effective in this group of patients with relatively low levels of disability.

Cost effectiveness analysis of the UK BEAM trial suggests that for patients with slightly more disabling back pain, physiotherapy in the form of manipulation and exercise is cost-effective compared with best care delivered by a General Practitioner.³⁰⁶ It is becoming clear from higher quality trials that the outcomes associated with different types of physiotherapy intervention differ only slightly.²⁶³
^{306 311 326 336 357} In the trial of manual therapy versus brief pain management by Hays et al. (2005), there were no significant differences in mean health care costs between groups but brief pain management was associated with significantly fewer treatment sessions.³⁵⁸ The cost-effectiveness of treatment is an important consideration for health care providers and for patients if private costs are incurred, but if clinical outcomes and costs are similar then other factors should be taken into account, such as patient preference.³⁵⁹

Comparison of the costs of this trial with those of three other UK trials of back pain is not straightforward due to differences in intervention, baseline characteristics, disability levels and type of patients.^{306 355 358} However, in this trial and the UK BEAM trial the advice intervention was similar but given by different practitioners (physiotherapists or general practitioners). The total health care costs for patients in the advice group in this trial (including the additional physiotherapy sessions) (£204, SD £277) and the total costs for patients in the physiotherapy (£264, SD £287) arm were both cheaper than the advice intervention given by general practitioners (£346, SD £602) in the UK BEAM trial. This suggests that it is cheaper to employ physiotherapists to deliver advice, in spite of the fact that this may lead to patients receiving additional physiotherapy treatments.

Cost implication for patients and purchasers

The cost implications of the trial reported in this thesis are that patients with minimal back pain are better off financially if they attend for one session of physiotherapy advice only. For those with more disabling pain a short course of manipulative therapy or exercise appears to be cost effective compared with advice.³⁰⁶

Issues raised following publication of the trial

Publication of the trial results in 2003 caused considerable debate within the physiotherapy profession due to over zealous media coverage by The Times, Daily Mail, The Guardian and Independent newspapers.³⁶⁰⁻³⁶³

The heterogeneous population, common to most back pain trials, was raised as a possible reason that differences were not found between groups.^{364 365} Sub-group analysis was not pre-specified in the trial reported in this thesis and was avoided in the analysis to prevent spurious conclusions being drawn.³⁶⁶ The assumption that certain treatments are effective for some but not others is not a new concept and most clinicians perceive that subgroups exist for low back pain and they are recognisable, particularly to those trained in manipulative therapy.¹⁴ At the International Primary Care Back Pain Forum held in 1995, a group of back pain researchers proposed 'establishing valid sub groups of low back pain' as part of the research priorities.^{367 368} It is not surprising that slow progress has been made in this field, as sub grouping patients with back pain is a highly contentious paradigm, not least because it is difficult to get consensus between and within professional groups. Various sub group classifications have been investigated.^{6 369-372} Researchers have attempted to make predictive rules to identify those who are likely to respond to

spinal manipulation^{369 373} or spine stabilisation exercises.³⁷⁴ An alternative classification tool has been developed that classifies patients depending on the presence of potentially modifiable physical and psychological risk factors.³⁷⁰ To date there is little evidence that sub-grouping changes treatment outcome but researchers are attempting to tackle this difficult issue using randomised controlled trial designs. Brennan et al (2006)³⁷¹ randomised acute and sub/acute patients into three treatment groups (manipulation, spine stabilisation exercises and specific exercises) and found no differences between groups. They demonstrated large differences in disability scores when subgroups, based on signs and symptoms used to guide treatment decision making, were analysed. This was a small study with post hoc subgroup analysis and poor follow up (66%) which limits the external validity of the authors' conclusions that outcomes improved when sub grouping was used to guide treatment decision-making.

Ten years after sub-grouping was proposed as a research priority it remains a challenge for the treatment of low back pain.³⁷⁵ The trial in this thesis was not designed to address this issue and it will take high quality, innovative trials to produce convincing evidence. Thereafter, universal acceptance of the classification tools will be essential, by all professionals, in order to have any impact on clinical practice.

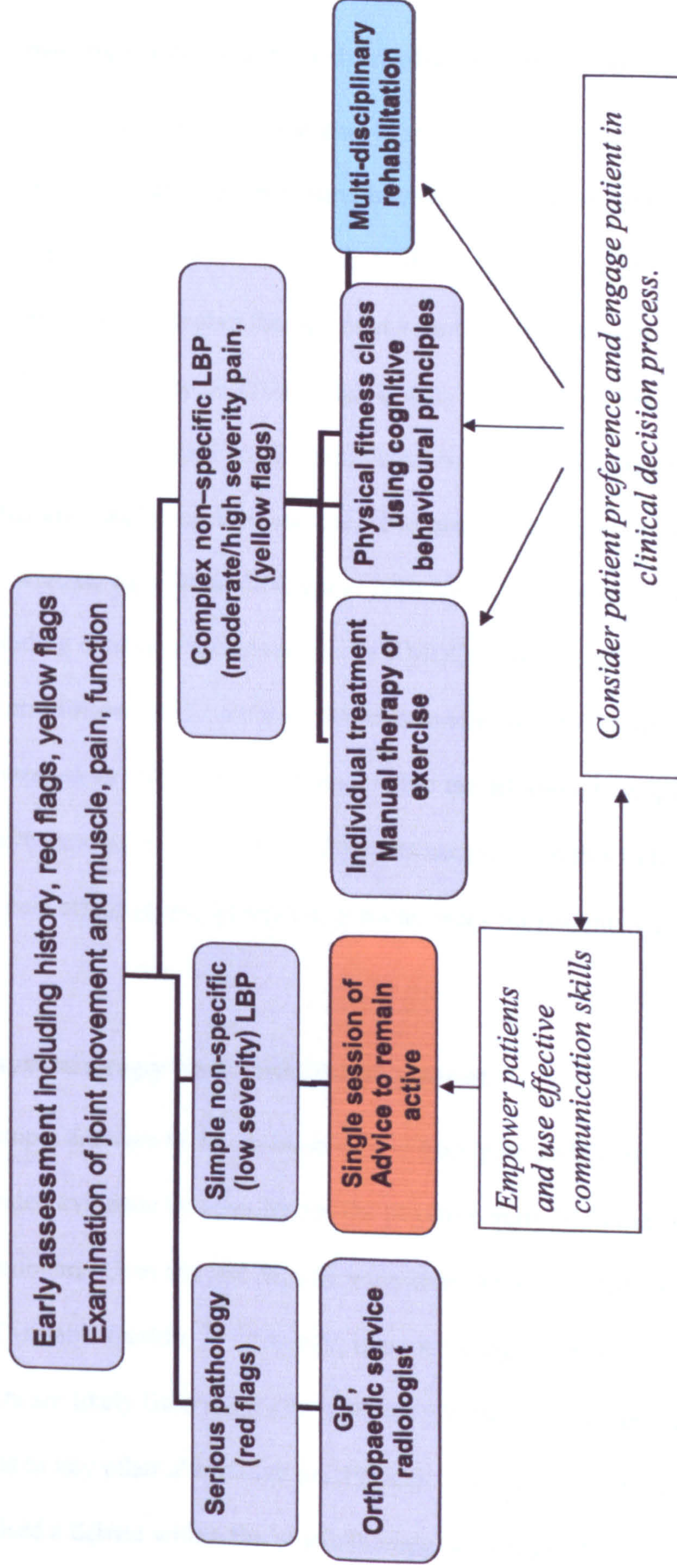
The trial in this thesis was criticised³⁶⁴ for providing too many different types of treatment by varying grades of staff but it was designed, and did reflect, the everyday lottery of physiotherapy provision in the NHS. Most therapists should recognise the methods of provision provided in this study as being common in many

departments.⁶² The trial results cannot tell us which treatments work best for low back pain, but what they do indicate is that widely practised models of physiotherapy provision are overall no better than a simple, intervention of assessment and advice for patients with mild to moderate low back pain.³⁷⁶ A single session of good advice is an acceptable method of treatment for many patients.³⁷⁷ In a feasibility study that evaluated prompt access to physiotherapy treatment in primary care more than 70% of patients were satisfied and successfully treated with a single visit. This indicated that this type of treatment can be a useful approach for selected patients.³⁷⁸ A single session of brief advice may only provide small treatment effects, but it fits into the model of triage for physiotherapy management of low back pain (See Figure 17). Innovative care pathways for back pain are being established in some parts of the UK that include this method of managing patients.³⁷⁹ Some may argue that it is unreasonable to expect patients with chronic pain to improve or be satisfied with one session of advice.³⁴⁰ That may be the case for those with more severe pain and disability but patients with chronic pain, as demonstrated in this thesis and cohort studies,³⁸⁰ can present with mild pain that fluctuates very little over time. If less time is spent on patients who will, at best gain small benefits, more time would be available to develop evidence based multi-disciplinary programmes for more complex patients with sub-acute and chronic pain where larger treatment gains have been demonstrated.^{11 21}

Physiotherapy time is costly^{11 21 62} and it is essential that it is used to best effect but where there are minimal or no difference in costs and outcome of different treatment

interventions, then it seems reasonable to consider patients preference within the limits of evidence based practice for patients with more severe disabling pain.

Figure 18 Model of triage for physiotherapy management of low back pain



Is alternative therapy more effective than physiotherapy for back pain?

There has been an increasing trend for patients to seek alternative therapy (i.e. chiropractic therapy, osteopathy, acupuncture, massage, and homeopathy) to alleviate back symptoms. However, no strong evidence has emerged over the last decade that suggests that alternative therapy is any more beneficial than physiotherapy.³⁸¹ In a recently published high quality USA trial of 444 patients with acute low back pain, patients were randomised to either usual care or a choice of alternative therapies including acupuncture, chiropractic treatment or massage therapy. There were no significant differences between the groups in reduction of symptoms, including disability measured on the RMDQ, at the short term (5 and 12 week) or long term follow up (52 weeks). Patients randomised to the alternative therapy group were more satisfied with treatment but the additional complementary therapy was more expensive.³⁸² Further research is necessary in this field to investigate the cost effectiveness of treatment preferences for patients with chronic low back pain.

Changing physiotherapy back pain management

There are no simple answers to the problem of low back pain and the trial in this thesis has provided evidence that challenges the physiotherapy NHS management of this common problem. Over the last decade researchers have reported vast amounts of evidence, of variable quality.^{21 251} Overall, there is strong evidence that only small treatment effects are likely from most interventions whether they are provided by physiotherapists or any other alternative practitioner. The positive aspect of this trial is that it has raised a debate within the physiotherapy profession. The results may

give physiotherapist more confidence to offer one off sessions of advice with the knowledge that the intervention, for selected patients, is as effective as offering additional treatment. Future research may provide stronger evidence for physiotherapy management possibly using sub grouping tools. Physiotherapists may be more effective in reducing back pain disability if they get more involved in developing health policy research and community work rather than spending time treating patients individually, particularly those with minimal disability. The Australian media campaign described in chapter nine was successful in using the bio-psychosocial messages in The Back Book to change community beliefs regarding back pain, GP beliefs and management and reduce claims for back pain.²⁹⁷ Successful implementation of this type of initiative in the UK would require change within the profession, government and financial support.

Conclusions

This study demonstrates that routine physiotherapy treatment for mild to moderate low back pain, generally practiced in the UK, is no more effective than an advice session given by a physiotherapist. The trial was rigorously completed to reduce bias and maximize internal and external validity however it is not possible to rule out threats caused by loss to follow up and potential selection bias. In comparisons with other back pain studies, the population recruited in this trial reported only mild/moderate disability that was most likely a subgroup of the total low back pain referrals. Despite these limitations the results of the trial are likely to reflect routine NHS patients and practice for this population. The NHS costs were similar at 12 months in both groups due to the additional costs incurred by patients in the advice group who went onto have additional treatment. However, private out of pocket expenses were higher in the physiotherapy group suggesting that a one off session of advice should be considered for patients with minimal disability. This trial provides physiotherapists with evidence of what not to do, rather than fulfilling the original objective of finding evidence to support physiotherapy in the NHS, but it could make an impact on physiotherapy management of back pain by encouraging new initiatives that in due course may improve quality of care.

The analysis of the outcome data suggests that the Oswestry Disability Index was a responsive primary measure for this population of patients and a valid indicator of change. It was the most specific to change and able to detect deterioration as well as improvement, compared with other back pain specific, generic and patient specific measures. In this context, the Oswestry Disability Index appeared to have an

advantage over the Roland and Morris Disability questionnaire and some domains of the SF-36, in scale width. Whilst the main outcomes appeared to be valid measures for this group of back pain patients, further qualitative analysis, nested within randomised controlled trials would be useful to capture information that is not measured on standard questionnaires. This may be particularly important where small differences are likely to be observed between interventions.

The systematic review of brief bio-psychosocial advice demonstrated that the effect of this type of intervention in isolation is, at best small. However, changes in fear avoidance beliefs should contribute to reduction of disability and pain in the longer term.

During the time between implementation and completion of this trial progress has been made in the field of back pain research. Standards have been set to improve the methodological quality and reporting of trials and the benefits of these standards are evident in recent publications. The small treatment effects found in this study are similar to those found in other recently reported higher quality trials suggesting that this common trend needs to be considered when designing future trials.

This research has contributed to European guidelines for the management of back pain²¹ and has helped to shape recommendations that require change within the NHS. There are obvious barriers to implementation of change within the NHS including physiotherapists' and patients' beliefs and expectations about treatment effectiveness, training and NHS organisational issues. These obstacles are surmountable but require vision, additional funding in some areas, enthusiasm and collaboration of all professionals involved in the management of low back pain.

Appendix 1 Quality index for assessment of systematic reviews

Oxman and Guyatt’s index of scientific quality assessment of systematic reviews^{83 96}

1) Were the search methods used to find evidence (original research) on the primary questions stated?	Yes	partially	no
2) Was the search for evidence reasonably comprehensive?	Yes	Can’t tell	no
3) Were the criteria used for deciding which studies to include in the overview reported?	Yes	partially	no
4) Was bias in the selection of studies avoided?	Yes	Can’t tell	no
5) Were the criteria used for assessing the validity of the included studies reported?	Yes	partially	no
6) Was the validity of all studies referred to in the text assessed using appropriate criteria? (either in selecting for inclusion or in analysing the studies cited)	Yes	Can’t tell	no
7) Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?	Yes	partially	no
8) Were the findings of the relevant studies combined appropriately relative to the primary question the overview addresses?	Yes	Can’t tell	no
9) Were the conclusions made by the authors supported by data and /or analysis reported in the overview?	Yes	partially	no

10. How would you rate the scientific quality of the overview?

The score for question 10 is based on the answers to the first 9 questions. If the can’t tell option is used one or more times the review is likely to have minor flaws at best. If the no option is used on question 2, 4, 6 and 8 the review is likely to have major flaws.

0-2= extensive flaws; 3-4 =major flaws; 5-6 =minor flaws; 7-minimal flaws.

For question 8, if no attempt was made to combine findings, and no statement is made regarding the inappropriateness of combining findings, No was ticked. If a summary estimate was given anywhere in the abstract, discussion or summary section of the paper, and it was not reported how the estimate was derived, no was ticked.

For question 9 to be scored as Yes data must be reported that supports the main conclusions regarding the primary questions that the overview addressed.

Appendix 2. Tables of randomised controlled trials of physiotherapy intervention for low back pain

Randomised controlled trials evaluating physiotherapy intervention for acute and sub-acute low back pain (prior to 1996)

Author and number recruited	Intervention	Outcome (% follow up)	Results	Quality score ⁸⁵
Lindsrom et al 1992 ³⁸³ n=103	Graded exercise and education programme for 1 week or GP care and physiotherapy	Return to work, range of motion, abdominal muscle endurance, and back muscle endurance	Average sick leave in the graded exercise group was 12.1 (SD 18.4) compared with 19.6 (SD 20.7) in the control group. At 1 year spinal mobility and fitness were greater in the graded activity group.	7/10
Stonkovic and Johnell 1990 ¹³³ n=100	McKenzie method of assessment and treatment or mini backschool	Return to work, sick-leave, pain recurrence, patients' ability to self help, pain and movement. 70% at 5 years	McKenzie superior in 5/7 outcome variables at 1 year. Only 1 variable (recurrence of pain) was significant at 5 years	4/10
Faas et al. 1993 ¹³¹ n=473	Exercise (flexion +isometric abdominals) placebo ultrasound or usual care form GP +written back education	Number and duration of recurrences using VAS for pain Nottingham health profile. Good compliance and low drop out at 1 year (13%)	NO differences between groups in number of recurrences. Exercise group had shorter duration of pain. No difference in duration of pain and functional outcome at 1 year. GP care group more often referred for physiotherapy. NO positive benefit of exercise over placebo	6/10

Malminavaara et al 1995 n=196	Bed rest, Back mobilising exercises, continuing ordinary activity	At 3 and 12 weeks ODI, pain, ability to work, lumbar flexion, number of days absent for work	Patients in control group recovered faster than exercise and bed rest groups. Recovery was slowest in bed rest group.	8/10
Waterworth 1985 ¹²⁶ n=72	Flexion and extension exercise, shortwave diathermy and ultrasound Vs spinal manipulation Vs NSAIDS	Pain (4 point scale) or spinal mobility after 4 and 12 days.	No significant differences between groups.	4/10
Nwuga ¹²⁵ N=51	Isometric flexion and abdominal muscles and microwave therapy Vs manipulation	Spinal flexion and straight leg raise testing	Manipulation significantly better than exercise	4/10

Continued overleaf.....

Farrell (1982) 124 N=48	Isometric flexion abdominal exercise Vs manipulation and mobilisation	Recovery speed	The manipulation group was symptom free in significantly less days.	4/10
Davies (1982) 123 n=43	Extension and shortwave diathermy Vs Isometric flexion and shortwave diathermy Vs shortwave diathermy	Flexion, pain and recovery speed at 2 and 4 weeks	No significant differences between groups	3/10
Delitto (1993) 130 n=24	McKenzie extension and mobilisation Vs Flexion exercises	Recovery on the Oswestry Disability Index at 3 and 5 days	Significantly more improvement in the McKenzie extension group	3/10
Nwuga (1985) 119 n=62	McKenzie extension Vs Flexion exercises	Change in pain after 6 weeks	McKenzie exercises significantly better than Williams exercise.	3/10

Continued overleaf.....

Mathews ³⁸⁴ N=291	Cyriax manipulation Vs Infrared heat	% of people recovered in 2 weeks. Patients sub- grouped depending on limitation in straight Leg raise test	Manipulation group recovered significantly in those with limited SLR but no differences between groups in patients with less limited SLR	4/10
Bergquist (1977) ³⁸⁵ n=147	Manipulation Vs SWD Vs Back school	Mean number of days until recovery	Backschool significantly better than SWD but no other significant differences	4/10
Glover (1974) ³⁸⁶ N=84	Manipulation Vs placebo SWD	Pain relief on VAS post treatment and 3 and 7 days	No significant differences between groups	4/10
Blomberg (1994) ³⁸⁷ N=101	Manipulation Vs active routine physiotherapy	Pain scores on VAS at 1,2 and 4 months	Manipulation group significantly less pain	4/10
Wreje (1992) ³⁸⁸ N=39	Sacro-iliac joint mobilisation Vs Massage	Pain VAS after 3 weeks and sick leave and analgesic consumption	No difference between pain but sick leave and analgesic consumption significantly less in manipulation group	2/10
Godfrey (1984) ³⁸⁹ N=81	Manipulation Vs massage and electrical stimulation	Scales quantifying symptoms, activities of daily life, mobility, tenderness to palpation, limitation of motion on testing, and forward flexion.	No significant differences between groups	2/10

Larson (1980) ³⁹⁰ N=82	Traction + corset +bed rest Vs Corset +bed rest	Number of patients improved after 1, 3 and 12 weeks	Traction significantly better after 1 and 3 weeks only	4/10
Matthews (1975) ³⁹¹ N=143	Traction (5 days per week) Vs Infrared heat treatment (3 times a week for 2-3weeks)	Recovery after 2 weeks	No significant differences between groups	3/10

Randomised controlled trials evaluating physiotherapy treatment for sub-acute and chronic low back pain (prior to 1996)

Author	Intervention	Outcome measures	Results	Quality score 85
Beursken et al 1995 ⁶⁷ N=151	High dose traction Vs Sham traction	Global perceived effect, severity of main complaint, functional status, and pain	No difference between groups in Intention to treat analysis or per protocol. Traction not effective for back pain	7/10
Heijden (1995) ¹⁵⁴ N=23	Continuous traction at 30%-50% of body weight for 20 minutes , 3 times a week for 4 weeks VS Continuous traction at 0-25% body weight	Pain and functional status	No significant differences between groups	3/10
Postachini et al 1988 ³⁹² n= 398	Chiropractic treatment Vs, physiotherapy Vs back school, Vs diclofenac, gel (placebo)	Forward spinal flexion, Straight leg raise, and VAS pain, muscle strength	Manipulation, physiotherapy and back school more effective than placebo over 6 months.	3/10
Klaber Moffett et al ³⁹³ n=92	Back school (3x 1hour sessions)and exercise	VAS pain score, ODI, spine mobility, activity test knowledge	Backschool more effective for pain and function but no difference in activity knowledge at 4 months	4/10

Continued overleaf.....

Hurri et al. ³⁹⁴ N=188	Backschool (6 x 1 hour sessions)	VAS pain scores, ODI, spine mobility, work absence, knowledge	Small changes in pain and function but no change in knowledge at 12 months	3/10
Hansen et al 1993 ¹³⁶ n=121	Intensive dynamic back exercise, physiotherapy (isometric exercise for trunk and legs) Placebo (hot pack and sham traction) 8 sessions for 4 weeks	Pain level Overall treatment effect Work load	Both physiotherapy groups reduced pain compared to the placebo at 12 month follow up. Sub group analysis suggested that males improved more with the less intense exercise and females improved more with intensive exercise.	5/10
Koes et al 1993, Koes et al 1992 ^{395 396} n=256	Manual therapy, Physiotherapy (exercise, massage, electrotherapy, GP management, Detuned Short wave therapy or ultrasound for placebo	Physical function and ROM Sickness impact profile	At 3 weeks no differences between manual therapy and placebo groups At 6 and 12 weeks no difference between manual therapy and placebo. At 1 year manipulation and physiotherapy groups had slightly better outcome than GP group	6/10

Continued overleaf.....

Meade et al 1990 ¹⁴⁵ n=741 (acute and chronic)	Chiropractic manipulation, secondary care physiotherapy (exercise, electrotherapy, advice; no manipulation)	Oswestry Disability Index (ODI), Straight leg raise and lumbar flexion	Increased benefit in ODI in chiropractic group (short and long term; 2 years). Not all differences were significant	5/10
Manniche et al 1988 ¹¹⁶ ¹³⁷ n=105	30 sessions of intensive extension exercise, 6 sessions of intensive exercise massage and mild exercise	11 point pain scale daily activities Schrober test Spinal mobility Drug use	Intensive exercise significantly more effective than both groups in all measures at post treatment and 6 months.	6/10
Turner (1990) ³⁹⁷ N=96	Aerobic exercise VS Aerobic exercise and behavioural therapy VS behavioural therapy Vs waiting list control	McGill pain questionnaire and sickness impact profile	At 6 and 12 month follow-ups there were no significant differences between groups	4/10
Frost 1995 ¹⁴⁰ n=81	Fitness programme (8, 1 hour sessions) +backschool or backschool, low intensity exercises advised to carry out at home	Oswestry Disability Index, Pain diaries, Pain self efficacy Pain locus of control Shuttle walking test General Health questionnaire	Both groups improved but fitness group improved more at 8 weeks and 6 months (86% follow up) in all outcomes but locus of control.	6/10

Randomised controlled trials evaluating patient education for acute low back pain (prior to 1996)

Author	Intervention	Outcome (% follow up)	Results	Quality score 85
Cherkin et al 1996 ¹⁴⁸ N=293	Usual care and back pain booklet or 15 minute session with a clinical nurse +back booklet and follow up	Satisfaction with care, perceived knowledge, participation in exercise, functional status, symptom relief, health care use 1, 3, 7, and 52 weeks after intervention	Higher satisfaction and perceived knowledge, and exercise participation in nurse intervention at one week. No differences in worry, functional status or health care use at any follow up.	5/10
Roland and Dixon 1989 ²⁶⁰	21 page advice booklet on spinal mechanics and LBP management or usual GP care	Consultation rates and hospital admissions during at 12/12 and amount of sick leave. Patient knowledge on back pain Patient knowledge on back pain	No difference between groups in % consultations in 1st 2 weeks of trial. After two weeks, referral to hospital and physiotherapy less common in booklet group. No differences in sickness absence after 1 year.	3/10 Date of birth used for randomisation.

Appendix 3. Physiotherapy managers collaboration statement

Appendix 4

Direct Line: Oxford (01865)
Switchboard: (01865) 741155
Fax: (01865) 742348



NUFFIELD ORTHOPAEDIC CENTRE

Windmill Road, Headington, Oxford OX3 7LD

Our ref:

Your ref:

Dr Jim Elliott
Regional R&D Manager (East)
Anglia and Oxford RHA
Institute of Public Health
University Forvie Site
Cambridge, CB2 2SR

17th November 1995

Dear Dr Elliott

Re: Evaluation of the Oxfordshire Physiotherapy Service for patients with low back pain.
A multicentre randomised controlled trial.

We have agreed to support and collaborate with grant applicants applying for funding to carry out this multicentre trial. We will take responsibility for the research physiotherapist in our departments if the project is financially supported by the Anglia and Oxford Regional Health Authority.

Yours sincerely

Barbara Fingstrom
Therapy Services Manager
Nuffield Orthopaedic Centre NHS Trust

Claire Thomas
Superintendent Physiotherapist
Churchill Hospital
(Oxford Radcliffe Trust)

Emy Pilgrim
Superintendent Physiotherapist
Radcliffe Infirmary NHS Trust

Jeanette Munson
Superintendent Physiotherapist
Horton General Hospital NHS Trust

Karen Bastin
Physiotherapy Manager
Oxfordshire Community Hospitals

NUFFIELD ORTHOPAEDIC
CENTRE NHS TRUST

Chairman: Frank Davies OBE CBE
Chief Executive: Colin Jones MBE FRCGS MRSM

**Appendix 4. Ethics letters, consent form, GP letter,
GP summary and patient information sheet**

OXFORDSHIRE ETHICS APPROVAL LETTER



NURSING & ALLIED PROFESSIONS RESEARCH ETHICS COMMITTEE

THE JOHN RADCLIFFE

Manor House
Headley Way, Headington
Oxford OX3 9DZ

Tel: 01865 222692/222547
Fax: 01865 222699

Our Ref. LC/KLB/1237

30 January, 1997

Ms Helen Frost
Director of Physiotherapy Research
Nuffield Orthopaedic Centre NHS Trust

Dear Helen,

RE NAPREC: 1237 - Evaluation of the Oxfordshire Physiotherapy Service for patients with low back pain. A multicentre randomised controlled trial comparing the physiotherapy service with brief advice on back care.

We have now received the letter of indemnity from the Nuffield Orthopaedic Centre NHS Trust and are happy to give final approval to your study.

Best wishes.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'Lindsey Coombes'.

Mr Lindsey Coombes
Chairman
Nursing & Allied Professions Research Ethics Committee

WEST BERKSHIRE ETHICS APPROVAL LETTER

WEST BERKSHIRE LOCAL RESEARCH ETHICS COMMITTEE

Tel: 0118 982 2900
Fax: 0118 982 2790

57/59 Bath Road
Reading
Berkshire RG30 2BA

PLEASE QUOTE 80/99

22 June 1999

Mrs H Frost
Director of Physiotherapy Research
Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford OX3 7LD

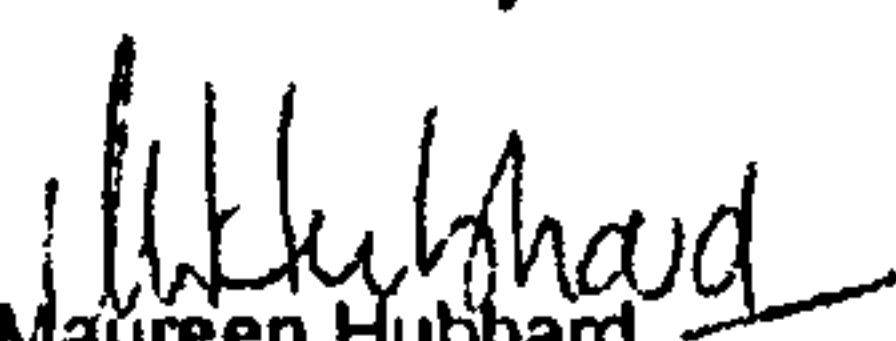
Dear Mrs Frost

EVALUATION OF PHYSIOTHERAPY TREATMENT FOR PATIENTS WITH LOW BACK
PAID. A MULTICENTRE RANDOMISED CONTROLLED TRIAL COMPARING MANUAL
THERAPY AND EXERCISE WITH BACK CARE AND ADVICE

Thank you for the revised documents relating to the above study which were passed to the
Chairman of the West Berkshire LREC

Ethical approval has now been granted to the proposal and the Committee wishes you
success with it. Members look forward to receiving copies of any publications arising from
the research.

Yours sincerely


Maureen Hubbard
Administrator
West Berkshire LREC

CONSENT FORM

OXFORDSHIRE PHYSIOTHERAPY LOW BACK PAIN TRIAL

CONSENT FORM

(Please circle as appropriate)

Have you read the Patient Information Sheet?	Yes	No
Have you had the opportunity to ask questions and to discuss this study?	Yes	No
Have you received satisfactory answers to your questions?	Yes	No
Have you received enough information about the study?	Yes	No

Do you understand:

• that you are free to withdraw from the trial at any time?	Yes	No
• that if you do withdraw, you do not have to give any reason?	Yes	No
• and that if you do withdraw, this will not affect your care?	Yes	No

Please sign your name here: _____

Please print your name here in block letters: _____

Date: ____/____/____
day month year

Hospital (eg. NOC, Churchill...): _____

Please return this form to the Trial Research Therapist. Thank you.

PATIENT INFORMATION SHEET

Oxfordshire physiotherapy low back pain study

Introduction

We are asking if you will help us with a study aiming to assess current physiotherapy treatment. There are a lot of different types of treatment available for people with low back pain but at present we are unsure which one is the best, particularly in the long term. A clinical trial is the only way to find out which treatment is the most beneficial.

What will the study involve?

If you agree to take part in the study we would ask you to attend for an assessment with a research physiotherapist before and after your treatment. This assessment would take approximately 1 hour in which time we would ask you to complete questionnaires about your back pain and general health.

Treatment

After you have seen the research physiotherapist you would be referred to another physiotherapist on the same day for treatment. If you agree to participate in the study neither you nor the physiotherapist can choose which treatment you receive. You would be allocated to one of two types of treatment by randomisation. Both groups include currently available physiotherapy treatment. The treatment would be either:

Advice and a back care booklet given during one session. This would include exercise and activity advice to help with your back problem at home and work.

or

Exercise and/or manual therapy and a back care booklet. The physiotherapist would decide how many appointments you would need.

There are no risks involved in the assessment or treatment and any information taken would be strictly confidential.

Follow up assessment

Two, six and twelve months after your initial assessment we would send questionnaires to your home with a stamped addressed envelope for you to complete and return. These questionnaires would take approximately 20 minutes to complete and would help us to assess the effectiveness of the treatment in the long term.

General information

We hope to recruit between 270 and 300 patients in the study from seven physiotherapy departments in the Oxfordshire area and you would be helping us and other patients in the future if you take part. However, you are under no obligation to take part in the study and if you do agree you could leave at any time without affecting your normal care in any way. We suggest that you keep this information sheet and show it to anyone concerned with your medical care.

Summary

If you decide to join the study your back problem would be assessed by a physiotherapist and you would be allocated to one of two treatment groups.

The treatment would be advice and a back care booklet or exercise and/or manual therapy and a back care booklet.

The treatment you would receive is not experimental in any way but normal physiotherapy treatment.

If you take part in the study you could withdraw at any stage without affecting the quality of your care.

If you have any further questions or problems please do not hesitate to contact the research physiotherapist in your area.

Name and telephone number included.

Thank you for taking the time to read this information

INFORMATION GIVEN TO GENERAL PRACTITIONERS

Dear Doctor

Re:

OXFORD PHYSIOTHERAPY LOW BACK PAIN TRIAL

Thank you for referring this patient for physiotherapy.

We have been funded by the Arthritis and Rheumatism Council for two years to carry out a multicentre randomised controlled trial in which the effectiveness of physiotherapy for patients with subacute and chronic low back pain will be evaluated. We would like to include your patient in the trial with your consent.

Your patient will be sent an information sheet explaining the trial in detail and invited to take part by a research physiotherapist. Following consent, they will be assessed and then randomly assigned to one of two treatment groups. They will receive treatment at the hospital to which they have been referred.

We will assume that you have no objection to your patient being involved in this trial unless we hear to the contrary. If you have any queries about the content of the physiotherapy treatment, please do not hesitate to contact the Low Back Pain Trial Research Coordinator (01865 227662).

Enclosed is a summary information sheet outlining the plan of the trial.

Thank you for your help.

Yours sincerely,

Farida Barma
Trial Research Therapist

Oxfordshire Physiotherapy Low Back Pain Trial

Funded by the Arthritis Research Campaign

Summary

Introduction

This study aims to evaluate the benefits of physiotherapy treatment for sub-acute and chronic low back pain. Standardised physiotherapy treatment and advice on back care will be compared with back care advice alone. The study design is a randomised controlled trial and we hope to recruit 300 patients from seven centres in Oxfordshire.

Assessments

All patients would be assessed before treatment by a research therapist and followed up at 2, 6 and 12 months by postal questionnaires. The questionnaires include well validated disease specific and generic health outcome measures.

Intervention

All patients would receive 'The Back Book' which has been compiled by experts in the field of low back pain and offers back care advice. Patients would be randomised to one of two treatment groups.

EITHER;

An assessment with a physiotherapist and a maximum of six sessions of standardised physiotherapy including exercise and/or manual therapy, advice on self management and specific back care advice

OR

A single session with a physiotherapist in which the patient would be assessed and receive advice on self management and specific back care advice.

Neither the patient nor the research therapist would be able to choose the treatment group to which the patient will be assigned.

Further information

If you have any questions or would like more information concerning the trial please contact Helen Frost, Director of Physiotherapy Research at the Nuffield Orthopaedic Centre NHS Trust or Tricia Carver, Trial Coordinator (01565 (2)27662).

Appendix 5. Back pain specific, patient specific and generic questionnaires

The following questionnaires were completed by the patients at baseline, 2, 6 and 12 months.

1. Oswestry Disability Index
2. Roland and Morris Disability Questionnaire
3. Patient Specific Activity Questionnaire
4. SF-36 questionnaire

1. OSWESTRY DISABILITY INDEX

Please answer **every** section. Mark the **one box only** in each section that most describes you today.

Section 1 - Pain Intensity

- ☐ I have no pain at the moment
- ☐ The pain is very mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is fairly severe at the moment
- ☐ The pain is very severe at the moment
- ☐ The pain is the worst imaginable at the moment

Section 2 - Personal Care (Washing, etc)

- ☐ I can look after myself normally without causing extra pain
- ☐ I can look after myself normally but it is very painful
- ☐ It is painful to look after myself and I am slow and careful
- ☐ I need some help but manage most of my personal care
- ☐ I need help every day in most aspects of self care
- ☐ I do not get dressed, wash with difficulty and stay in bed

Section 3 - Lifting

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives extra pain
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g. on a table
- ☐ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- ☐ I can lift only very light weights.
- ☐ I cannot lift or carry anything at all

Section 4 - Walking

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me walking more than 1 mile (1.6km)
- ☐ Pain prevents me walking more than ¼ mile (500 metres)
- ☐ Pain prevents me walking more than 100 yards (100 metres)
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time and have to crawl to the toilet

Section 5 - Sitting

- ☐ I can sit in any chair as long as I like
- ☐ I can sit in my favourite chair as long as I like
- ☐ Pain prevents me from sitting for more than 1 hour
- ☐ Pain prevents me from sitting for more than ½ hour
- ☐ Pain prevents me from sitting for more than 10 minutes
- ☐ Pain prevents me from sitting at all

Section 6 - Standing

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than 1 hour
- ☐ Pain prevents me from standing for more than ½ hour
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

Section 7 - Sleeping

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain
- ☐ Because of pain I have less than 6 hours sleep
- ☐ Because of pain I have less than 4 hours sleep
- ☐ Because of pain I have less than 2 hours sleep
- ☐ Pain prevents me from sleeping at all

Section 8 - Sex life (if applicable)

- ☐ My sex life is normal and causes no extra pain
- ☐ My sex life is normal but causes some extra pain
- ☐ My sex life is nearly normal but is very painful
- ☐ My sex life is severely restricted by pain
- ☐ My sex life is nearly absent because of pain
- ☐ Pain prevents any sex life at all

Section 9 - Social Life

- ☐ My social life is normal and causes me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sport, etc.
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted social life to my home
- ☐ I have no social life because of pain

Section 10 - Travelling

- ☐ I can travel anywhere without pain
- ☐ I can travel anywhere but it gives extra pain
- ☐ Pain is bad but I manage journeys over two hours
- ☐ Pain restricts me to journeys of less than one hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from travelling except to receive treatment

2. THE ROLAND-MORRIS DISABILITY QUESTIONNAIRE

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you *today*. As you read the list, think of yourself *today*. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember; only tick the sentence if you are sure it describes you today.

1. I stay at home most of the time because of my back. ☐
2. I change position frequently to try and get my back comfortable ☐
3. I walk more slowly than usual because of my back ☐
4. Because of my back I am not doing any of the jobs that I usually do around the house ☐
5. Because of my back, I use a handrail to get upstairs ☐
6. Because of my back, I lie down to rest more often ☐
7. Because of my back, I have to hold on to something to get out of an easy chair ☐
8. Because of my back, I try to get other people to do things for me ☐
9. I get dressed more slowly than usual because of my back ☐
10. I only stand for short periods of time because of my back ☐
11. Because of my back, I try not to bend or kneel down ☐
12. I find it difficult to get out of a chair because of my back ☐
13. My back is painful almost all the time ☐
14. I find it difficult to turn over in bed because of my back ☐
15. My appetite is not very good because of my back pain ☐
16. I have trouble putting on my socks (or stockings) because of the pain in my back ☐
17. I only walk short distances because of my back ☐
18. I sleep less well because of my back ☐
19. Because of my back pain, I get dressed with help

from someone else ☐

- 20. I sit down for most of the day because of my back ☐
- 21. I avoid heavy jobs around the house because of my back ☐
- 22. Because of my back pain, I am more irritable and bad tempered with people than usual ☐
- 23. Because of my back, I go upstairs more slowly than usual ☐
- 24. I stay in bed most of the time because of my back ☐

3. PATIENT SPECIFIC ACTIVITY QUESTIONNAIRE

OXFORDSHIRE PHYSIOTHERAPY LOW BACK PAIN TRIAL

PATIENT SPECIFIC ACTIVITY QUESTIONNAIRE

Patient's name: _____

From the following list please tick up to **three** activities or movements which are affected by your back pain.

- | | |
|--|---|
| <input type="checkbox"/> Lying in bed | <input type="checkbox"/> Bending for a long time |
| <input type="checkbox"/> Turning in bed | <input type="checkbox"/> Standing slightly bent |
| <input type="checkbox"/> Getting out of bed | <input type="checkbox"/> Twisting your back |
| <input type="checkbox"/> Sleeping | <input type="checkbox"/> Bending with a twisted back |
| <input type="checkbox"/> Rising from a chair | <input type="checkbox"/> Working (job) |
| <input type="checkbox"/> Getting seated | <input type="checkbox"/> Hobbies |
| <input type="checkbox"/> Sitting for a long time | <input type="checkbox"/> Carrying about 5kg (eg shopping bag) |
| <input type="checkbox"/> Getting in or out of a car | <input type="checkbox"/> Carrying about 10kg (eg 1 year old child) |
| <input type="checkbox"/> Driving | <input type="checkbox"/> Repeated lifting |
| <input type="checkbox"/> Cycling | <input type="checkbox"/> Visiting friends or family |
| <input type="checkbox"/> Standing | <input type="checkbox"/> Going out |
| <input type="checkbox"/> Standing for a long time | <input type="checkbox"/> Sexual activities |
| <input type="checkbox"/> Light housework
(eg dusting, washing-up) | <input type="checkbox"/> Picking up something light from floor
(eg a handkerchief) |
| <input type="checkbox"/> Heavy housework
(eg vacuuming, mopping) | <input type="checkbox"/> Picking up something heavy from floor
(eg full bin bag) |
| <input type="checkbox"/> Walking around house | <input type="checkbox"/> Sport |
| <input type="checkbox"/> Walking (generally) | <input type="checkbox"/> Travelling |
| <input type="checkbox"/> Running | <input type="checkbox"/> Other (please specify) _____ |
| <input type="checkbox"/> Going up stairs | <input type="checkbox"/> _____ |
| <input type="checkbox"/> Going down stairs | <input type="checkbox"/> _____ |

Now list the activities or movements you chose in order of their importance.

1.

2.

3.

In the following boxes we would like you to tell us how **difficult** the activity/movement has been to perform, how **important** it is to you and how **frequently** you have to perform it.

Please tell us by putting **one** mark on each line scale.

Example:

How difficult was it to perform this activity/movement during the last week?

no problemsimpossible

Activity 1:

How difficult was it to perform this activity/movement during the last week?

no problemsimpossible

How important was it for you to perform this activity/movement during the last week?

not importantvery important

How often did you perform this activity/movement during the last week

neververy often

Activity 2: _____

How difficult was it to perform this activity/movement during the last week?

no problems _____ impossible

How important was it for you to perform this activity/movement during the last week?

not important _____ very important

How often did you perform this activity/movement during the last week

never _____ very often

Activity 3: _____

How difficult was it to perform this activity/movement during the last week?

no problems _____ impossible

How important was it for you to perform this activity/movement during the last week?

not important _____ very important

How often did you perform this activity/movement during the last week

never _____ very often

4. SF-36 QUESTIONNAIRE

OXFORDSHIRE PHYSIOTHERAPY LOW BACK PAIN TRIAL

PATIENT'S NAME: _____

The following questions ask for your views about how well you are able to do your usual activities. If you are unsure about how to answer any question, please give the best answer you can and make any of your own comments if you like.

1. In general, would you say your health is:
(please tick one box only)

<input type="checkbox"/>	Excellent
<input type="checkbox"/>	Very good
<input type="checkbox"/>	Good
<input type="checkbox"/>	Fair
<input type="checkbox"/>	Poor

2. Compared to one year ago, how would you rate your health in general now?
(please tick one box only)

<input type="checkbox"/>	Much better now than one year ago
<input type="checkbox"/>	Somewhat better now than one year ago
<input type="checkbox"/>	About the same
<input type="checkbox"/>	Somewhat worse now than one year ago
<input type="checkbox"/>	Much worse now than one year ago

The following questions are about activities you might do during a typical day.
Please tick ☒ one box on each line.

3. Does your health limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Bending, kneeling or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Walking more than a mile (1.6 km)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Walking half a mile (500 metres)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Walking 100 yards (100 metres)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Bathing and dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (please tick either Yes or No to each question)

	Yes	No
a) Cut down on the amount of time you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
b) Accomplished less than you would like	<input type="checkbox"/>	<input type="checkbox"/>
c) Were limited in the kind of work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
d) Had difficulty performing the work or other activities (eg it took extra effort)	<input type="checkbox"/>	<input type="checkbox"/>

5. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?
(please tick either **Yes** or **No** to each question)

	Yes	No
a) Cut down on the amount of time you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>
b) Accomplished less than you would like	<input type="checkbox"/>	<input type="checkbox"/>
c) Didn't do work or other activities as carefully as usual	<input type="checkbox"/>	<input type="checkbox"/>

6. During the *past 4 weeks*, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups? (Please tick one box only)

<input type="checkbox"/>	Not at all
<input type="checkbox"/>	Slightly
<input type="checkbox"/>	Moderately
<input type="checkbox"/>	Quite a bit
<input type="checkbox"/>	Extremely

7. How much *bodily* pain have you had during the *past 4 weeks*?
(Please tick one box only)

<input type="checkbox"/>	None
<input type="checkbox"/>	Very Mild
<input type="checkbox"/>	Mild
<input type="checkbox"/>	Moderate
<input type="checkbox"/>	Severe
<input type="checkbox"/>	Very severe

8. During the past 4 weeks, how much did *pain* interfere with your normal work (including work both outside the home and housework)?
(Please tick one box only)

- ☐ Not at all
- ☐ A little bit
- ☐ Moderately
- ☐ Quite a bit
- ☐ Extremely

These questions are about how you feel and how things have been with you during the *past month*. (For each question, please indicate the one answer that comes closest to the way you have been feeling)

9. How much time during *the past month*: (Please tick one box on each line)

		All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a)	Did you feel full of life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b)	Have you been a very nervous person	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c)	Have you felt so down in the dumps that nothing could cheer you up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d)	Have you felt calm and peaceful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e)	Did you have a lot of energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f)	Have you felt downhearted and low	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g)	Did you feel worn out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h)	Have you been a happy person	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i)	Did you feel tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j)	Has your health limited your social activities (like visiting friends or close relatives)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. Please choose the answer that best describes how true or false each of the following statements is for you. (Please tick one box on each line)

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
a) I seem to get ill more easily than other people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) I am as healthy as anybody I know	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) I expect my health to get worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) My health is excellent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix 6. Patient assessment forms and patient diary

1. Patient assessment form = Data collected at baseline.
2. Patient assessment form - 6 month follow up = Data collected at 6 months (The patient assessment form at 2 months was identical to the patient assessment form at 6 months but referred to the previous 2 months)
3. Patient assessment form - 12 month follow up = Data collected at 12 months.
4. Patient diary. The diary issued to each patient at the baseline assessment to help recall of appointments and medication.

OXFORDSHIRE PHYSIOTHERAPY LOW BACK PAIN TRIAL

PATIENT ASSESSMENT FORM

Surname:	_____	First name:	_____
Title:	_____	Date of birth:	____/____/____
		Sex:	male <input type="checkbox"/> female <input type="checkbox"/>
Address:	_____		
Postcode:	_____	Telephone no:	Home: _____ Work: _____
Patient's hospital no:	_____		

PATIENT'S RANDOMISATION GROUP (1 OR 2): _____

Referred by:

Consultant _____ GP _____ Via triage clinic _____

1. How long have you had this episode of low back pain? _____

2. When did you experience your first episode of back pain? _____

3. Today and over the last week, have you experienced any of the following?

low back pain ☐

buttock pain ☐

thigh pain ☐

pain extending beyond the knee ☐

4. Today and over the last week, have you experienced any pins and needles or numbness in your legs?

Yes ☐ No ☐

5. Today and over the last week, have you had any problems controlling your bladder or bowels?

Yes ☐ No ☐

6. Have you received any previous treatment for low back pain?

Yes ☐ No ☐

If yes, please specify which treatment by placing a tick in the appropriate box:

GP	<input type="checkbox"/>
consultant	<input type="checkbox"/>
osteopathy	<input type="checkbox"/>
chiropractic	<input type="checkbox"/>
NHS physiotherapy	<input type="checkbox"/>
private physiotherapy	<input type="checkbox"/>
other (please specify) _____	

How long ago did you have your last treatment? _____

7. Are you currently in paid employment? Yes ☐ No ☐

8. Do you drive? Yes ☐ No ☐

9. How many hours do you spend driving each week? _____

10. Do you smoke? Yes ☐ No ☐

If yes, approximately how many cigarettes per day? _____

If you smoke a pipe, approximately how many ounces of tobacco do you smoke per day? _____

11. Are you claiming any compensation for any injury/accident related to your back pain?

Yes ☐ No ☐

12. Are you taking any medicines at present?

Yes ☐ No ☐

	NAME OF MEDICINE	QUANTITY PER DAY (mg)
Anti-inflammatory		
Pain killers		
Anti-depressants		
Others		

13. Have you been involved in any exercise/sport over the last 4 weeks?

Yes ☐ No ☐

If yes, which if any of these activities have you done in the past 4 weeks?
(Please tick appropriate box)

swimming	<input type="checkbox"/>
weight training	<input type="checkbox"/>
aerobics/keep fit	<input type="checkbox"/>
cycling	<input type="checkbox"/>
jogging/running	<input type="checkbox"/>
team sport (eg football, rugby, hockey)	<input type="checkbox"/>
racquet sports (eg. tennis, squash, badminton)	<input type="checkbox"/>
yoga	<input type="checkbox"/>
athletics	<input type="checkbox"/>
walks of 2 miles or more	<input type="checkbox"/>
heavy housework/DIY/gardening	<input type="checkbox"/>
other sports or exercises (please specify):	<input type="text"/>

If yes, approximately how many times in the last week have you done any of these activities?

less than 1 ☐ 1-2 ☐ 3-4 ☐ 5 or more ☐

OXFORDSHIRE PHYSIOTHERAPY LOW BACK PAIN TRIAL

PATIENT ASSESSMENT FORM
6 month follow-up

This questionnaire refers to the past 4 months since you completed your last follow-up questionnaires.

Surname: _____ First name: _____ Title: _____

Trial no: _____ Date of birth: ____/____/____

1. Over the past 4 months, do you feel you have benefited from the physiotherapy treatment you received at the beginning of the Trial 6 months ago?

Yes ☐ No ☐

On a scale of 0-10, how much benefit do you think you have gained from the treatment? (0 = no benefit, 10 = maximum benefit). Please circle appropriate number.

0 ____ 1 ____ 2 ____ 3 ____ 4 ____ 5 ____ 6 ____ 7 ____ 8 ____ 9 ____ 10

2. During the past 4 months, have you consulted a doctor or therapist or received any further treatment for your low back pain?

Yes ☐ No ☐

If yes, please specify by placing a tick in the appropriate box:

GP	<input type="checkbox"/>	how many times?	_____
consultant	<input type="checkbox"/>	how many times?	_____
osteopathy	<input type="checkbox"/>	how many times?	_____
chiropractic	<input type="checkbox"/>	how many times?	_____
NHS physiotherapy	<input type="checkbox"/>	how many times?	_____
Private physiotherapy	<input type="checkbox"/>	how many times?	_____

other (please specify): _____

3. Over the past 4 months, have you been admitted to hospital because of your back pain?

Yes ☐ No ☐

If yes, how many days did you spend in hospital? _____

4. Has your doctor prescribed any medicines or creams for your back pain over the past 4 months?

Yes ☐ No ☐

Prescribed medicines/creams:

Date	How many items were on the prescription?	How many of these were related to your back pain?

5. Over the past 4 months, have you bought any medicines or creams for your back pain?

Yes ☐ No ☐

Medicines/creams you bought without a prescription:

Date	How many medicines/creams? (count each item seperately)	How many of these were related to your back pain?	Total cost of all back pain items

6. Over the past 4 months, have you had to take any sick leave from work because of your back pain?

Yes ☐ No ☐ Not applicable ☐

How many days sick leave did you take? _____

7. Have you been involved in any exercise/sport over the last 4 months?

Yes ☐ No ☐

If yes, which ones? (Please tick all boxes that apply).

- | | |
|--|--------------------------|
| swimming | <input type="checkbox"/> |
| weight training | <input type="checkbox"/> |
| aerobics/keep fit | <input type="checkbox"/> |
| cycling | <input type="checkbox"/> |
| jogging/running | <input type="checkbox"/> |
| team sport (eg football, rugby, hockey) | <input type="checkbox"/> |
| racquet sports (eg. tennis, squash, badminton) | <input type="checkbox"/> |
| yoga | <input type="checkbox"/> |
| athletics | <input type="checkbox"/> |
| walks of 2 miles or more | <input type="checkbox"/> |
| heavy housework/DIY/gardening | <input type="checkbox"/> |
| other sports or exercises (please specify): | <input type="text"/> |

Approximately how often in the last 4 months have you done any of these activities?

- | | |
|------------------------|--------------------------|
| less than once a month | <input type="checkbox"/> |
| once a month | <input type="checkbox"/> |
| once a fortnight | <input type="checkbox"/> |
| once a week | <input type="checkbox"/> |
| twice a week | <input type="checkbox"/> |
| more than twice a week | <input type="checkbox"/> |

OXFORDSHIRE PHYSIOTHERAPY LOW BACK PAIN TRIAL

PATIENT ASSESSMENT FORM
12 month follow-up

This questionnaire refers to the past 6 months since you completed your last follow-up questionnaires.

Surname: _____ First name: _____ Title: _____
Trial no: _____ Date of birth: ____/____/____

1. Is your back pain *better, just the same* or *worse* after the physiotherapy advice/treatment you received 12 months ago? Please tick the appropriate box.

better ☐ same ☐ worse ☐

On a scale of 0-10, how much benefit do you think you have gained from the advice/treatment? (0 = no benefit, 10 = maximum benefit). Please circle the appropriate number.

0 _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8 _ 9 _ 10

2. During the past 6 months, have you consulted a doctor or therapist or received any further treatment for your low back pain?

Yes ☐ No ☐

If yes, please specify by placing a tick in the appropriate box:

GP	<input type="checkbox"/>	how many times?	_____
consultant	<input type="checkbox"/>	how many times?	_____
osteopathy	<input type="checkbox"/>	how many times?	_____
chiropractic	<input type="checkbox"/>	how many times?	_____
NHS physiotherapy	<input type="checkbox"/>	how many times?	_____
Private physiotherapy	<input type="checkbox"/>	how many times?	_____
other (please specify): _____			

3. Over the past 6 months, have you been admitted to hospital because of your back pain?

Yes ☐ No ☐

If yes, how many days did you spend in hospital? _____

4. Has your doctor prescribed any medicines or creams for your back pain over the past 6 months?

Yes ☐ No ☐

Prescribed medicines/creams:

Date	How many items were on the prescription?	How many of these were related to your back pain?

5. Over the past 6 months, have you bought any medicines or creams for your back pain?

Yes ☐ No ☐

Medicines/creams you bought without a prescription:

Date	How many medicines/creams? (count each item seperately)	How many of these were related to your back pain?	Total cost of all back pain items

6. Over the past 6 months, have you had to take any sick leave from work because of your back pain?

Yes ☐ No ☐ Not applicable ☐

How many days sick leave did you take? _____

7. Have you been involved in any exercise/sport over the last 6 months?

Yes ☐ No ☐

If yes, which ones? (Please tick all boxes that apply).

- swimming ☐
- weight training ☐
- aerobics/keep fit ☐
- cycling ☐
- jogging/running ☐
- team sport (eg football, rugby, hockey) ☐
- racquet sports (eg. tennis, squash, badminton) ☐
- yoga ☐
- athletics ☐
- walks of 2 miles or more ☐
- heavy housework/DIY/gardening ☐
- other sports or exercises (please specify): _____

Approximately how often in the last 6 months have you done any of these activities?

- less than once a month ☐
- once a month ☐
- once a fortnight ☐
- once a week ☐
- twice a week ☐
- more than twice a week ☐

PATIENT DIARY

Patient's Name: _____

Thank you for attending your initial assessment for the Low Back Pain Trial. We would like to follow your progress over the next year by collecting information from you in 2, 6 and 12 months time. We will be asking about any hospital visits or appointments with your doctor connected with your back pain. We would also like to know about any visits to complimentary practitioners (e.g. Osteopath, Chiropractor etc). To help you remember when these appointments took place and the details of any medication you took, we would like you to use this diary so that it is easier for you to provide the information we need when we contact you.

If you have any problems filling in your diary, please do not hesitate to contact Jane Hainsworth, the Trial Administrator (01865 227662/227723) who will be happy to help.

Thank you for your support.

Helen Frost
Director of Physiotherapy Research

HOSPITAL

This section of your diary should be completed any time you visit hospital as an outpatient.

Date of visit	Reason for visit	Who did you see? (i.e. consultant, nurse, physiotherapist)	Was the visit related to your back pain?

If you have more visits, please continue on a separate sheet of paper and attach to your diary.

GENERAL PRACTITIONER OR PRACTICE NURSE

This section of your diary should be completed any time you visit your general practitioner or practice nurse.

Date of visit	Reason for visit	Who did you see? (e.g. GP, Practice Nurse)	Was the visit related to your back pain?

If you have more visits, please continue on a separate sheet of paper and attach to your diary.

COMPLIMENTARY PRACTITIONERS OR PRIVATE PHYSIOTHERAPISTS

This section should be completed any time you visit an Osteopath, Chiropractor, Private Occupational Therapist, Private Physiotherapist, Acupuncturist or other complimentary medicine practitioner.

Date of visit	Reason for visit	Who did you see? (e.g. Osteopath, Chiropractor, etc)	Was the visit related to your back pain?

If you have more visits, please continue on a separate sheet of paper and attach to your diary.

HOME VISITS

This section should be completed any time a General Practitioner, Practice Nurse or a Complimentary Practitioner visits your home.

Date of visit	Reason for visit	Seen by: (GP, Nurse, Complimentary Practitioner)	Was the visit related to your pack pain?

If you have more visits, please continue on a separate sheet of paper and attach to your diary.

MEDICATION

This last section relates to any medicines or anti-inflammatory/muscle relaxing creams you have been prescribed or bought yourself.

Prescribed medicines/creams:

Date	How many items were on the prescription?	How many of these were related to your back pain?

Medicines/creams you bought without a prescription:

Date	How many medicines/creams? (count each item separately)	How many of these were related to your back pain?	Total cost of all back pain items

Thank you for completing this diary

Please keep it in a safe place as the information you record here will be helpful when you complete your follow-up questionnaires.

Appendix 7. Patient treatment questionnaire completed by clinician

OXFORDSHIRE PHYSIOTHERAPY LOW BACK PAIN TRIAL

PATIENT TREATMENT QUESTIONNAIRE

Please complete and store this in the Patient Treatment Questionnaire folder. They will be collected by Patricia Carver, Research Coordinator, at the end of the Trial.

PATIENT'S NAME: _____ DOB: _____

PHYSIOTHERAPIST'S NAME: _____

SECTION 1

Which techniques did you use to treat this patient?
(please tick appropriate box)

advice and The Back Book ☐

mobilisation ☐

manipulation ☐

soft tissue techniques ☐

Please give details: _____

exercise ☐

Please give details: _____

heat treatment ☐

cold treatment ☐

How many treatment sessions has this patient had? ☐

How much time has this involved? Hours_____ Minutes_____

On a scale of 0-10, how much benefit to you think this patient has gained from the treatment? (0 = no benefit, 10 = maximum benefit).

0____1____2____3____4____5____6____7____8____9____10

PTO...

SECTION 2

Complete this section ONLY if the patient has not had the treatment to which they were allocated or has received additional treatment.

Details of the patient's treatment: _____

Number of additional sessions: _____

Why was this necessary? _____

Thank you for taking the time to complete this form.

Appendix 8. Search strategy

#	Search History
1	randomized controlled trial.pt.
2	Randomized Controlled Trials/mt (Methods)
3	"Controlled Clinical Trial (Publication Type)"/
4	random allocation.mp. or Random Allocation/
5	Double-Blind Method/
6	Single-Blind Method/
7	or/1-6
8	Animal/ not human.mp. (mp=title, original title, abstract, name of substance word, subject heading word)
9	7 not 8
10	clinical trial.pt.
11	exp clinical trials/
12	(clin\$ adj25 trial\$).tw.
13	Placebos/
14	placebo\$.tw.
15	random\$.tw.
16	Research design/
17	(latin adj square).tw.
18	((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (mask\$ or blind\$)).tw.
19	or/10-18
20	19 not 8
21	20 not 9
22	comparative study/
23	exp evaluation studies/
24	Follow-up studies/
25	Prospective studies/
26	(control\$ or prospective\$ or volunteer\$).tw.
27	cross-over studies/
28	or/22-27
29	28 not 8

Continued overleaf.....

30	29 not (9 or 21)
31	9 or 21 or 30
32	Low back pain/
33	low back pain.tw.
34	backache.tw.
35	lumbago.tw.
36	or/32-35
37	31 and 36
38	back book.tw.
39	(book\$ or pamphlet\$ or leaflet\$).tw.
40	patient education.tw.
41	advice.mp.
42	minimal intervention.mp.
43	or/38-42
44	37 and 43

Appendix 9. Verification of methodological criteria

Item 1) Scored positive if it was clear that a truly random (unpredictable) assignment sequence was used. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriately randomised.

Item 2) Scored positive if the procedure used for assignment to study groups provided assurance of adequate concealment. Assignment was generated by an independent person not responsible for determining the eligibility of patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.

Item 3) Scored positive if the withdrawal/drop-out rate (that is the number of randomised patients minus the number of patients at the main moment of effect measurement divided by all randomised patients and multiplied by 100) was less than 20%.

Item 4) Scored positive if co-interventions were avoided in the design of the study or were equally divided among the intervention groups.

Item 5) Scored positive if patients were blinded regarding treatment allocation and the method of blinding was appropriate. As it is difficult to blind the patients for exercise therapy, the credibility of the treatments should be evaluated and treatments should be equally credible and acceptable to patients to be scored positive for this item.

Item 6) Scored positive if the observers were blinded regarding treatment allocation and the blinding was evaluated and adequate. If only self-reported (by the patients) outcome measures were used and no outcomes were measured by an observer, item 6) was scored negative unless treatments were demonstrated to be equally credible.

Item 7) Scored positive if all patients were included in the analysis as part of the intervention group allocated by randomisation, irrespective of non-compliance and co-interventions. If loss to follow-up is substantial (20% or more), an intention-to-treat analysis, as well as an alternative analysis which accounts for missing values (e.g., a worst-case analysis), should be performed.

Item 8) Scored positive if compliance with the treatment program was measured and satisfactory in all study groups.

Item 9) Scored positive if the study groups were similar at baseline regarding the most important prognostic factors, i.e., duration of complaints, value of outcome measures, age, recurrence status, and absence or presence of radiation.

Item 10) Scored positive if the care providers were blinded regarding treatment allocation and the blinding was evaluated and adequate. Similar to item 5 this item would receive a positive score if there was evidence that all of the care providers believed they were delivering the 'effective' intervention.

Appendix 10. Data collection forms for systematic review

Basic information for study ID: Burton 1999

Method

Randomisation Generated random list for each practice. Treatment allocation given to patients either by GP or osteopath in a sealed unmarked opaque envelope at the end of the consultation. Outer envelope included an instruction sheet and baseline questionnaire and inner envelope contained either The Back Book or the Handy Hints book	Blinding Patients and clinician blind to intervention, outcome assessment blind. No code break before end of analysis	Intention to treat - Loss to Follow-up ITT analysis not documented and loss to follow up more than 20% (77% at 2 weeks, 72 at 3 months and 78% at 12 months). Clinical records reviewed for 92% of patients
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Participants

N 162 patients; 83 in experimental group, 79 in control	Age 42.6 (SD10.9) experimental group 44.7 (12.2) control. 17-70 range	Sex 89 female 73 male	Type of LBP: new and recurrent LBP <3 months
Country UK north east England	Hospital 5 primary GP care practices and 1 private osteopath clinic	Period of Study NO data?	Other participants. None
Inclusion criteria		Exclusion Criteria	
LBP of less than 3 month duration		Possible serious spinal disease or nerve root pain	
		Unable to read and write in English	
		Primary psychiatric illness	
		History of alcohol or drug abuse	
		Loss of time from work or received an health care in previous 3months	

Intervention (including description, when started, frequency, duration & when stopped etc)
Experimental intervention was The Back Book. Patients seen by GPs were given general re-assurance.
Control intervention was the Handy hints booklet
Additional intervention for both groups included general re-assurance and advice from the GP as well as sick certification and analgesia where appropriate. The osteopathic patients received similar advice and reassurance as well as manipulative therapy (mean 4.3 sessions) with individual recommendations for non-prescription analgesic and sick-leave.

Overall length of follow-up:

Outcomes

Outcomes	Tick if available	How measured	When done
Fear avoidance beliefs		Fear avoidance beliefs questionnaire (the subscale of this questionnaire on fear avoidance beliefs about physical activity was the main focus and recorded as FABphys) 0-24 0= best	Baseline, 2 weeks, 3 months and 1 year
Pain	Usual pain not available	VAS 0-100 0 =no pain 100 = worst pain. Measured as; Usual pain Worst pain At best pain	A/A
Disability		Roland disability questionnaire 0-24 0 = no disability 24 = severely disabled)	A/A
Beliefs about the inevitable consequence of back pain		Back beliefs questionnaire (BBQ) 9-45 45= best	

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